21ST CENTURY TECHNOLOGY FOR 21ST CENTURY CURES

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON COMMUNICATIONS AND TECHNOLOGY

AND THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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C O N T E N T S

[1] Mr. Vockell did not answer submitted questions for the record by the time of printing.

21ST CENTURY TECHNOLOGY FOR 21ST CENTURY CURES

THURSDAY, JULY 17, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMUNICATIONS AND TECHNOLOGY,
JOINT WITH THE
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittees met, pursuant to notice, at 9:33 a.m., in room 2123, Rayburn House Office Building, Hon. Greg Walden (chairman of the subcommittee of Communications and Technology) presiding.

Members present: Representatives Walden, Upton, Barton, Shimkus, Pitts, Terry, Burgess, Blackburn, Gingrey, Scalise, Latta, Lance, Cassidy, Guthrie, Gardner, Kinzinger, Griffith, Bilirakis, Long, Ellmers, Waxman, Pallone, Eshoo, Green, DeGette, Butterfield, Barrow, Matsui, and Braley.

Staff present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Ray Baum, Senior Policy Advisor/Director of Coalitions; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Leighton Brown, Press Assistant; Noelle Clemente, Press Secretary; Andy Duberstein, Deputy Press Secretary; Paul Edattel, Professional Staff Member, Health; Gene Fullano, FCC Detailee; Kelsey Guyselman, Counsel, Communications and Technology; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Grace Koh, Counsel, Communications and Technology; Carly McWilliams, Professional Staff Member, Health; David Redl, Chief Counsel, Communications and Technology; Charlotte Savercool, Executive Assistant, Legislative Clerk; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Jean Woodrow, Director of Information Technology; Ziky Ababiya, Democratic Staff Assistant; Eric Flamm, Democratic FDA Detailee; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor; Margaret McCarthy, Democratic Professional Staff Member; Rachel Sher, Democratic Senior Counsel; Matt Siegler, Democratic Counsel; and Ryan Skukowski, Democratic Policy Analyst.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. We are going to call the hearing to order. Thank you all for being here this morning. Good morning and welcome. Today, the Subcommittee on Communications and Technology and

Subcommittee on Health joint hearing on the "21st Century Technologies for 21st Century Cures." I would like to thank all of our witnesses for testifying today. Your testimony is extraordinary and most helpful in our endeavors.

When Chairman Upton and I announced that we would begin the process in updating the Communications Act, we knew it would be a difficult but much-needed process. So I am pleased today to be joining the Communications Act update with another important Energy and Commerce Committee initiative, 21st century cures, the communications and technology sectors that are an enormous boost to our Nation's struggling economy due in part to the high investment and innovation in wireless technology and other devices.

As we craft the legislation to update our laws, it is essential to hear from a wide variety of people who are on the front lines of developing and using these types of technologies in all spaces. Their unique viewpoints and expertise will help inform our consideration as we move forward, as well as underscore exactly why we have undertaken these challenging efforts to revamp existing laws.

It makes sense to unite these two initiatives, as they are both critically important not only to industries that are crucial to the economy, but also for every person here. This is an opportunity to recognize the benefits wireless smartphones and devices can provide to improve an individual's health and the healthcare community.

We have seen examples of this intersection already from wearable devices that track activity, to the use of mobile apps reminding users of their individual health needs, to a patient's ability to easily and remotely communicate with their doctor through a telehealth device. The growth in this area has been remarkable. There is a technological revolution happening in the healthcare space.

In the communications and technology world, there has been a good deal of focus on the so-called virtuous cycle of technology; that is, the investment in devices and networks creates opportunities for app developers to create new and innovative uses for these devices, driving demand for consumers, which then spurs further investment. The healthcare technology field the perfect setting for this engine of invention and development.

As healthcare technologies proliferate, patients, doctors and researchers will realize the potential for the technology, and as a result, demand will increase. Increased demand means even greater incentive for investors to place their bets on the technology, which, in turn, spurs the cycle even further.

In reading the testimony submitted by our witnesses in advance of today's hearing, I was impressed by what they can already do in the healthcare field using technology that exists and what the potential is as we develop. In Mr. Misener's written testimony, he describes how leveraging cloud technology allowed scientists to conduct an experiment at a cost that was orders of magnitude less than it would have been using traditional data center and infrastructure. And I believe it was 39 years compressed into 9 hours. This is exactly what we are hoping to learn about today in more detail and how we can take advantage of these opportunities.

With that, again, thank you for being here.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Good morning and welcome to today's Subcommittee on Communications and Technology and Subcommittee on Health joint hearing, "21st Century Technology for 21st Century Cures." I would like to thank all of our witnesses for testifying today on this timely topic.

When Chairman Upton and I announced that we would begin the process of updating the Communications Act, we knew it would be a difficult, but much-needed, process. I am pleased today to be joining the Communications Act Update with another important Energy and Commerce Committee initiative, 21st Century Cures. The communications and technology sector has been an enormous boost to our Nation's struggling economy, due in part to the high investment and innovation in wireless technology and other devices. As we craft the legislation to update our laws, it is essential to hear from a wide variety of people who are on the front lines of developing and using these types of technologies in all spaces. Their unique viewpoints and expertise will help inform our consideration as we move forward, as well as underscore exactly why we have undertaken these challenging efforts to revamp existing laws.

It makes sense to unite these two initiatives, as they are both critically important not only to industries that are crucial to the economy, but also for every person here. This is an opportunity to recognize the benefits wireless smartphones and devices can provide to improve an individual's health and the health care community. We have seen examples of this intersection already, from wearable devices that track activity, to the use of mobile apps reminding users of their individual health needs, to a patient's ability to easily and remotely communicate with their doctor through a telehealth device. The growth in this area has been remarkable; there is a technological revolution happening in the health space.

In the communications and technology world, there has been a good deal of focus on the so-called virtuous cycle of technology; investment in devices and networks creates opportunities for app developers to create new and innovative uses for those services, driving demand from consumers, which then spurs further investment. The health technology field is the perfect setting for this engine of invention and development. As health care technologies proliferate, patients, doctors, and researchers will realize the potential for the technology, and as a result, demand will increase. Increased demand means even greater incentive for investors to place their bets on the technology, which in turn spurs the cycle even further.

In reading the testimony submitted by our witnesses in advance of today's hearing, I was impressed by what can already be done in the healthcare field using the technology that exists, and what the potential is as we developed. In Mr. Misener's written testimony, he describes how leveraging cloud technology allowed scientists to conduct an experiment at a cost that was orders of magnitude less than it would have been using traditional datacenters and infrastructure. This is exactly what we are hoping to learn more about today—how we can take advantage of what these companies are already experts at doing, be it technology or healthcare, and benefit everyone.

I hope that our diverse panel of witnesses today will take this opportunity to expand on the specific ways in which their particular organizations are contributing to this space and what opportunities they see for the future. While there are undoubtedly obstacles that remain before some of these technologies come to bear, this conversation is a good starting point and a way to highlight why it's worth working through the issues that arise. I would like to thank you all for being here today and I look forward to your testimony.

Mr. WALDEN. And I now recognize Mr. Pallone for 3 minutes.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you. Thank you, Chairman Pitts and Chairman Walden.

We are here today to discuss the ways in which promising new technologies may be harnessed by the healthcare industry to provide better quality care, inform healthcare research, and empower

Americans to better maintain their own health. The Subcommittee on Health has explored this issue in a number of different hearings this Congress, most recently in April, when we examined how 21st century technology can benefit patients. And what we have learned today and what I hope we will hear more about today is that these technologies may not just improve patient outcomes, but also have the potential to bring down the cost of care for everyday Americans and for the Nation.

Many health systems are responding to the Affordable Care Act's call to reduce costs and improve quality by adopting the use of technologies like electronic health records, health analytics, telemedicine and mobile health applications. By monitoring patient progress in real time, providers will limit costly readmissions and prevent the onset of advanced stages of disease. In fact, declining readmission rates played a significant role in slowing the growth of our Nation's health spending in the years following passage of the ACA, and in the long-term budget outlook published Tuesday, the CBO found that the decline in our health spending will allow the Medicare trust fund to remain solvent for an additional 6 years.

And this testifies to how the law is pushing providers to improve the quality of care, but also to the potential of health technology like telemedicine and patient tracking systems to relieve the financial burden of preventable conditions on the entire healthcare system.

In keeping with the ACA's embrace of preventive care, many of these technologies will help keep people healthy and enable patients with chronic disease to better manage their conditions on their own. The CDC estimates that 133 million Americans live with at least one chronic illness disease like diabetes, heart disease and cancer, and the treatment of chronic illness accounts for more than 75 percent of all health spending, so it should be clear that keeping Americans healthy must be a national priority. Additionally, with access to quality data, health researchers at the NIH and throughout the country will be better able to study the range of conditions which afflict Americans, research that can be used to develop more effective treatments and inform the practice of evidence-based medicine.

Meanwhile, health analytics will allow insurers to design value-based benefit plans which will reimburse providers for the quality and not the quantity of care they render. And with this monetary incentive, providers will more often invest in an ounce of prevention than wait to deliver a pound of care.

Many of the technologies discussed today can improve Americans' health, yet we must remember that the adoption of technology for its own sake does little good and can contribute to the escalating cost of medicine. We have to work to ensure that advances in health technologies serve to improve all Americans' health, stopping the onset of preventable conditions while not exacerbating health disparities along socioeconomic lines. And further, we must make certain that the transfer of these data and doctor-patient communications complies with Federal regulations and that Federal law ensures the confidentiality of patient data.

Our witnesses today represent firms developing these technologies, and I thank them for their testimony as well as their efforts to improve Americans' health.

And Mr. Chairman, I am looking forward to hearing what is now in the field and how this further contributes to the past work of our committee. Thank you.

Mr. WALDEN. Thank you, Mr. Pallone. Appreciate that.

Now we go to the chairman of the Health Subcommittee, Mr. Pitts, for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. Thank the chairman for this joint hearing of the Subcommittees on Communications and Technology and Health, and welcome all of our witnesses here this morning.

As part of our committee's 21st Century Cures Initiative, we are examining the discovery, development and delivery process to speed new treatments and cures to patients. One of the most promising avenues to facilitate this goal is new technology, and we are witnessing the impact of that technological innovation that it has played in every aspect of our economy. Technology has the potential to transform health care as well, and in doing so, address many of the challenges that we currently face. The question before us is, How do we ensure that our healthcare system can take advantage of the innovation going on in the tech world?

We now have mobile medical apps that can make health care more personalized, if we don't over regulate them. We have electronic health records that can be shared among various providers to help better coordinate the care we receive, if we can ensure they are interoperable. These and other technologies hold great potential for the future of health care and personalized medicine. In order to realize this potential, however, we are going to have to address barriers that currently make full integration difficult.

Our witnesses are here today to help us think through these technologies and the role they can play in a 21st century healthcare system. So I thank all of the witnesses for being here today.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

As part of our committee's 21st Century Cures Initiative, we are examining the discovery, development, and delivery process to speed new treatments and cures to patients.

One of the most promising avenues to facilitate this goal is new technology. We are witnessing the impact that technological innovation has played in every aspect of our economy.

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Our witnesses are here today to help us think through these technologies and the role they can play in a 21st century health care system.

Mr. PITTS. And as I yield back, I ask for unanimous consent to submit for the record a letter from the Telecommunications Industry Association.

Mr. WALDEN. Without objection, so ordered.

[The letter follows:]

TELECOMMUNICATIONS INDUSTRY ASSOCIATION
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July 16, 2014

The Honorable Greg Walden
U.S. House of Representatives
2182 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
U.S. House of Representatives
241 Cannon House Office Building
Washington, DC 20515

The Honorable Joe Pitts
U.S. House of Representatives
420 Cannon House Office Building
Washington, DC 20515

The Honorable Frank Pallone
U.S. House of Representatives
237 Cannon House Office Building
Washington, DC 20515

Dear Chairmen and Ranking Members:

The Telecommunications Industry Association (TIA), the leading trade association for global manufacturers, vendors, and suppliers of information and communications technology, wishes to thank you for holding a hearing this week to examine the intersection of technology and health care in the 21st Century. As the Committee on Energy & Commerce moves forward with the 21st Century Cures initiative, we urge you to consider the following:

Maximize the Benefits of Telehealth and Remote Patient Monitoring: A modern, 21st century healthcare system must leverage innovations in communications technologies. The known benefits of remote patient monitoring, which connects patients and health care providers virtually anytime, anywhere, include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill. A recent study also predicted remote monitoring will result in savings of $36 billion globally by 2018, with North America accounting for 75% of those savings[1]. Opportunities for Congress to bring about great improvements in this area include removing barriers to enhanced telehealth services in Section 1834(m) of the Social Security Act[2].

More Spectrum is Needed to Keep Pace With Exploding Demand: TIA would like to commend the Committee for their continued work on freeing up spectrum for commercial use. With a growing number of uses and users, innovative, next-generation devices, applications and services require spectrum availability for fixed and mobile broadband use. This can be achieved through further reallocation of federal spectrum, flexible regulations, and improved spectrum management.

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1 *See* Juniper Research, Mobile Health & Fitness: Monitoring, App-enabled Devices & Cost Savings 2013-2018 (rel. Jul. 17, 2013), available at http://www.juniperresearch.com/reports/mobile_health_fitness.

2 *See* 42 CFR § 410.78. As a recent example, TIA led a broad cross-section of stakeholders in the healthcare space in urging for newly-confirmed HHS Secretary Burwell to waive 1834(m) restrictions on Accountable Care Organizations in the Medicare Shared Savings Program. *See* http://bit.ly/1na1UrA.

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A Regulatory Framework Must Promote Innovation and Increase Regulatory Clarity: Outdated regulations that have restricted the use of telehealth have long been a hindrance to progress in this space. A flexible framework that carefully balances risk and benefit and provides regulatory clarity will facilitate competition and innovation. TIA also urges Congress to work to ensure coordination across all governmental entities in providing certainty to those in the healthcare space, from the healthcare provider to the vendors that enable care.

Realize the Full Potential of Meaningful Use Stage 3: In order to realize the full potential of the EHR Incentive Program, it is imperative that the remote monitoring of patient-generated health data be fully contemplated in Stage 3 of Meaningful Use definitions for electronic health records (EHRs)[3]. We also urge for the use of open standards for interoperability among all EHR systems.

Make Investment in Advanced Medical Device Technologies a National Priority: Certainty in sustained or increased federal investment in R&D is important and will help contribute to US leadership, but government policies must also provide incentives and facilitate strategic and robust investment from the private sector.

***

TIA thanks you again for holding this hearing, and we look forward to working with you on these important issues. For more information, please contact Danielle Coffey at (703)-907-7734 or by email at dcoffey@tiaonline.org.

Sincerely,

Grant E Seiffert

Grant Seiffert
President

[3] *See* http://bit.ly/1hLWth7.

Mr. WALDEN. We now turn to the gentlelady, my friend from California, Ms. Eshoo, for opening comments.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. ESHOO. Thank you, Mr. Chairman. And welcome to the witnesses. And I want to thank the leaders of the two subcommittees for having this joint hearing. I think it is a terrific idea and an important one, to talk about the combination, the intersection of technology and medicine. And I think that in both areas, it represents American genius, and that is why I find it so exciting.

My Silicon Valley District is the home of modern-day innovation. It really is the innovation capital of our country, of the world. It embodies an entrepreneurial spirit, and it attracts those who identify challenges and turn them into opportunities. They drive new technologies, expand education, and find creative ways to build a better world and to improve humankind.

The valley has a long history of pioneering technological advancements. After World War II, the development of the semiconductor industry, which is really the foundation of Silicon Valley, led the way to the desktop computer and then to the explosion of the Internet, which continues to flourish. And I could tick off a whole list of honor roll names of companies that are identified with the Valley.

What is equally important, in my view, in Silicon Valley, and it is not always widely recognized, are the parallel advancements in health care. My district is the birthplace of biotechnology in our country, and we have more biotechnology companies there than any other place in the country and in the world. So it is an eloquent statement about the region and what takes place.

There are hundreds of young companies developing the latest therapeutics, medical devices, diagnostics, genomic tests and wireless healthcare technologies. And the ability for these two industries, high technology and health care, to mature side by side has really yielded, I think, unparalleled advancements for patients and dramatically improved healthcare outcomes. So that the whole issue of the power of broadband and wireless connectivity, it is the intersection of technology and health care, I think is more dynamic than ever.

In Mountain View in my district, iHealth's blood pressure monitor is empowering individuals to take charge of their health care by wirelessly connecting this data to a smart phone. That used to be for James Bond. Now it is for the average person.

Similarly, Proteus, a Redwood City-based company is improving patient health care through an ingestible sensor which wirelessly sends information using blue tooth technology. I mean, this—it really is—it is not only cutting-edge, it is exciting and it is important.

I am very proud to have Dr. Dan Riskin here today from my district testifying. Thank you for coming across the country to do so. He is a serial entrepreneur. He is the founder of Health Fidelity and consulting faculty at Stanford University School of Medicine. So thank you, Dr. Riskin. And he serves on the eHealth Initiative

Leadership Council and collaborated with the Bipartisan Policy Center on their oversight framework for assuring patient safety and health information technology. Jeez, I thought only in Government did we have long titles like this, but I guess it is in academia as well.

So want to welcome all the distinguished witnesses here today. And, again, I thank the leadership of both of the subcommittees for putting this important hearing together.

Mr. WALDEN. Thank you.

Ms. ESHOO. And I yield back.

Mr. WALDEN. Thank the gentlelady.

We now turn to the chairman of the full committee, the gentleman from Michigan, Mr. Upton, for opening comments.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman.

With this hearing, we are going to continue our commitment to modernizing laws and regulations to keep pace with the breakneck speed of the innovation era. Two leading initiatives have been our Comm Act update, which seeks to update the 80-year-old laws governing the communications and technology sectors, and obviously 21st Century Cures, which aims to accelerate the pace of cures in treatments.

Today we have the unique opportunity to bring together two of our subcommittees and look at the intersection of these efforts and the ways in which new technology is enabling remarkable advances in medical care and treatment and research.

Our witnesses include established tech companies that are hoping to bring their expertise to bear on the challenges of modern health care as well as startups that are focused solely on tech solutions for patients and clinicians, from electronic health records, to cloud storage of genome research and apps that identify preventative health strategies, we are looking at the future of medicine. Technology is supporting proactive solutions, collaborative research, and improved communications between patients and their physicians.

Our committee has gone great lengths to encourage investment in innovation in the U.S. Tech sector, and there are few applications of that work more important than the health of all Americans. We have the opportunity to not only enable new cures, but accelerate the pace at which they are realized. By taking full advantage of available technology, the possibilities for the future of health care indeed gives us hope.

In June we held a round table to explore the opportunities and obstacles surrounding digital health care, and I look forward to continuing that conversation. It is my hope that this hearing, like the round table, will help us identify ways in which this committee and the Congress can support the adoption of lifesaving technologies in the healthcare sector. I thank you all for being here, and I yield back the balance of my time.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

With this hearing we continue our commitment to modernizing laws and regulations to keep pace with thebreakneck speed of the innovation era. Two leading initiatives have been our CommActUpdate, which seeks to update the 80-year-old laws governing the communications and technology sectors, and 21st Century Cures, which aims to accelerate the pace of cures and treatments. Today, we have the unique opportunity to bring together two of our subcommittees and look at the intersection of these efforts and the ways in which new technology is enabling remarkable advances in medical care and research.

Our witnesses include established tech companies that are bringing their expertise to bear on the challenges of modern health care as well as startups that are focused solely on tech solutions for patients and clinicians. From electronic health records to cloud storage of genome research and apps that identify preventive health strategies, we are looking at the future of medicine. Technology is supporting proactive solutions, collaborative research, and improved communications between patients and their doctors.

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I thank the witnesses for being here with us today and sharing their experiences as health tech innovators.

Mr. WALDEN. The gentleman yields back the balance of his time.

The Chair now recognizes the distinguished gentleman and former chairman of the committee, Mr. Waxman, for 3 minutes.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman.

This joint subcommittee hearing is a chance for members to learn more about the technological innovation taking place in our healthcare system. Technology can play an important role in expanding access to care, improving the quality of care, improving health outcomes, and reducing costs.

In recent years, we have witnessed incredible innovation in our healthcare system, venture capital funding for digital health companies is at a record level, new innovators are entering the industry every day. And it is not a coincidence that all of this innovation has occurred in the years since we passed the Affordable Care Act. As a managing director of a major startup incubator put it, "We are seeing a lot of tailwinds from the healthcare reform. It has put a lot of pressure on existing stakeholders to reduce costs."

It is also not a coincidence that this innovation is occurring following our unprecedented investment in expanding the use of health information technology through the Recovery Act. The number of doctors using these technologies has quadrupled in just 3 years. The percentage of hospitals using them has grown from 16 percent to 94 percent.

It is not a coincidence that we have seen all of this innovation with FDA and the FCC offering important guidance and using their enforcement discretion wisely. And it is not a coincidence that

we have seen this innovation at the same time that HHS has opened up vast amounts of data to the public while recognizing innovation with awards and grants to help startups shake up the health system.

I mention these important ways the Federal Government has helped foster a climate of innovation, because this hearing and the committee's 21st century cures initiative should focus on these successes.

I look forward to hearing from today's witnesses about what needs to be done to continue these trends that are improving our healthcare system every day. We should legislate only where appropriate and necessary, otherwise, we risk jeopardizing the integrity of a system that is already functioning quite well.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. WALDEN. Thank the gentleman for his opening comments. And now we go directly to the witnesses.

Thank you all again for submitting your testimony in advance. We appreciate that. And we will open up with Mr. Dave Vockell. Is that right? Did I say that correctly?

Mr. VOCKELL. Close enough.

Mr. WALDEN. And turn on that microphone.

Chief executive officer of Lyfechannel. We are delighted to have you here. Please proceed.

STATEMENTS OF DAVE VOCKELL, CHIEF EXECUTIVE OFFICER, LYFECHANNEL, INC.; DAN RISKIN, FOUNDER, HEALTH FIDELITY; PAUL MISENER, VICE PRESIDENT, GLOBAL PUBLIC POLICY, AMAZON; ROBERT JARRIN, SENIOR DIRECTOR, GOVERNMENT AFFAIRS, QUALCOMM INCORPORATED; AND JONATHAN M. NILOFF, VICE PRESIDENT AND CHIEF MEDICAL OFFICER, MCKESSON CONNECTED CARE & ANALYTICS

STATEMENT OF DAVE VOCKELL

Mr. VOCKELL. Good morning, Chairman Walden and Pitts. I am Dave Vockell, the CEO and founder of Lyfechannel, Inc. It is a great honor for me to be here today, and I want to thank you for the opportunity to testify on this very important topic of innovative technology and the current and potential impacts to population health.

I would like to briefly cover three topics today: first, a short overview of Lyfechannel to give you some context as to the role that startups can play in the rapidly evolving healthcare delivery landscape; second. I will cover three lessons learned and the "so what" that might inform how you evaluate health technology opportunities; and third, I am going to share a list of large insiders who I think are forward thinkers and innovators in working with new technology, and to try to discover what is next for healthcare delivery.

Lyfechannel, Inc., builds mobile patient programs that translate physician instruction into patient action, which help patients new to diabetes, pre-diabetes, COPD, heart health and smoking cessation begin to build basic good habits to support their chronic conditions. We also operate a preventive health program targeting the chief health officer of a household. We create programs that con-

nect the patient and their personal support team and their care providers through integration across mobile experiences and the provider's electronic health record.

Over the past 3 years, we have worked closely with patients, pharma companies, Government agencies, payers, EHR's, providers and other technology companies to translate changes in technology and consumer behavior into opportunities to impact long-term health. We have learned three important lessons relevant to consumer facing health. First, if you are not integrated into the existing patient flow, whether it would be the physician or the provider or payer, it is almost impossible to become part of a patient's health journey. Consumer health actions are not only the behaviors that new technology companies need to engage, but they are also hospital procedures, billing protocols, prescribing habits, hundreds of habits within the system that we need to be a part of.

Number two, technology doesn't change behavior, it just potentially creates a new access point to things that do change patient behavior. A cool app on your phone doesn't make you take your meds by reminding you or making a game out of it. You don't skip your Lipitor because it wasn't fun or because you forgot; you skip it for the basic human behavior that you feel great and you are not connecting your current health behavior to long-term health. Technology experiences that reinforce the drivers of good health behavior create patient-led, not technology-led solutions.

And finally, there remains a strong economic incentive not to release the data that will drive patient insights and recommendations for the next 10 years. Many payers do not release claims data that could fuel incredible insights into pinpointing health intervention opportunities, because they have a large business selling that data to pharma companies. Electronic health record companies don't make it simple to exchange data with other EHR's, because it reduces switching costs of moving to a different HR for a hospital.

There are a handful of innovative large institutions that unleashed great innovative momentum through aggressive piloting and partnership with third parties, and the pattern of their innovation is similar. They make public a problem they are trying to solve, they make data available to support solving that problem, and then they find a pathway to engaging technology innovators to solve that problem.

Here are a couple examples of those leading innovators. The Office of Disease Prevention and Health Promotion, under the guidance of Linda Harris, Ellen Langhans and Silje Lier of the ODPHP are pioneers in co-design of digital experiences incorporating health literacy principles. They not only engaged third-party technology companies against the goal of the ODPHP, but also systematically share their learnings with other Government and public sector groups to advance best practices and patient literacy around preventive health. Their Myfamily mobile program has been a pilot for the past 10 months and is about to release version 2, which includes EHR integration and connectivity with the new Apple Healthkit platform.

Boehringer-Ingelheim, under the guidance of Jon Doniger in their new business model group, aggressively engages new tech-

nology companies to help his organization understand the role that pharma could play in healthcare delivery in 10 years.

The Allscripts EHR platform under the leadership of Tina Joros has also embraced third-party developers and platform openness to tap into the power of technology innovators.

Johnson & Johnson, Robert J. Wood Hospital System, Box and CMS have also been aggressive in identifying problems, making data available to entrepreneurs and helping them try to solve their hardest problems.

In summary, we believe that technology companies that partner with large insiders and lead with patient behavior versus cool technology have the greatest opportunity to impact health outcomes in the next 10 years. There are some great innovators that should serve as a model, and no shortage of technology innovators with limitless energy and caffeine to try to impact population health.

Thank you again to the chairpersons and members of the subcommittee for your time today and the opportunity to participate in this hearing. I would love to answer any questions you have. Thank you.

[The prepared statement of Mr. Vockell follows:]

Congress of the United States

US House of Representatives
Committee on Energy and Commerce
Subcommittee on Communications and Technology
Subcommittee on Health
Washington, D.C.

Hearing on: 21st Century Technology for 21st Century Cures

July 17, 2014

Testimony of:

Dave Vockell
Chief Executive Officer
Lyfechannel, Inc.
San Francisco, CA

Testimony of Dave Vockell, Chief Executive Officer
Lyfechannel, Inc.
Committee on Energy and Commerce, Subcommittee on Communications and Technology, Subcommittee on Health
July 17, 2014

SUMMARY

Lyfechannel, Inc builds mobile patient programs that translate physician instruction into patient action. We help patients new to Diabetes, pre-Diabetes, COPD, heart health, and smoking cessation begin to build basic "good habits" to support their chronic conditions and also operate a preventive health program targeting the "Chief Health Officer" of a household.

Over the past three years we have worked closely with patients, pharma companies, payers, EHRs, providers and other technology companies to translate changes in technology and consumer behavior into opportunities to impact long term health. We have learned three important lessons relevant to any consumer-facing health technology.

1. If you are not integrated into the existing patient flow – whether it be with a physician or provider or payer – it is almost impossible to become part of a patient's health journey.
2. Technology doesn't change behavior, it just potentially creates a new access point to things that do change patient behavior
3. There remain strong economic incentives not to "release" the data that will drive patient insights and recommendations in the next 10 years

There are a handful of innovative large institutions that unleashed great innovative momentum through aggressive piloting and partnership with third parties.

4. The Office of Disease Prevention and Health Promotion
5. Boehringer-Ingelheim Pharmaceuticals
6. Allscripts
7. Johnson and Johnson
8. The Robert J Wood Hospital System
9. Box

Lyfechannel believes that technology companies that partner with "large insiders" and lead with patient behavior vs. cool technology have the greatest opportunity to impact health outcomes in the next 10 years.

Good morning. I am Dave Vockell, the CEO and Founder of Lyfechannel, Inc. It is a great honor for me to be here today, and I want to thank you for the opportunity to testify on the very important topic of innovative technology and the current and potential impact to population health.

I'd like to briefly cover three topics today:

- First, a short overview of Lyfechannel to give you some context as the role the startups can play in the rapidly evolving healthcare delivery landscape.
- Second, I'll cover three lessons learned and the "so what" that might inform how you evaluate health technology opportunities.
- Third, I'm going to share a list of large "insiders" who I think are forward thinkers and innovators in working with new technology to try and discover "what's next" health care delivery

Lyfechannel, Inc builds mobile patient programs that translate physician instruction into patient action. We help patients new to Diabetes, pre-Diabetes, COPD, heart health, and smoking cessation begin to build basic "good habits" to support their chronic conditions and also operate a preventive health program targeting the "Chief Health Officer" of a household. We create programs that connect the patient and their personal support team and their care providers through integration across mobile experiences and the provider's EHR (electronic health record). We recently won a CMS (Centers for Medicare and Medicaid Services) challenge to translate a recently released data set related to Medicare charges into a consumer-valuable tool.

Over the past three years we have worked closely with patients, pharma companies, government agencies, payers, EHRs, providers and other technology companies to translate changes in technology and consumer behavior into opportunities to impact long term health. We have learned three important lessons relevant to any consumer-facing health technology.

1. If you are not integrated into the existing patient flow – whether it be with a physician or provider or payer – it is almost impossible to become part of a patient's health journey. Consumer health actions are not the only behaviors that new technology companies need to engage if they hope to impact health at any scale. There is hospital procedure, billing protocol, prescribing habits – hundreds of "habits" within the system that need to be addressed, and to do it from the outside is still almost impossible.
2. Technology doesn't change behavior, it just potentially creates a new access point to things that do change patient behavior. A cool app on your phone doesn't make you take your meds by reminding you or making a game of it. You don't skip your Lipitor because it wasn't fun, or because you forgot, you skip it for the basic human behavior that "you feel great right now" and you're not connecting current health behavior to long term health. Technology experiences that reinforce the drivers of good health behavior create patient-led, not technology-led solutions.
3. There remain strong economic incentives not to "release" the data that will drive patient insights and recommendations in the next 10 years. Many payers do not release claims data that could fuel incredible insights into pinpointing health intervention opportunities because they have a large business selling that data to pharma companies. Electronic Health Record companies do not make it simple to exchange data with other EHR companies because it reduces the switching cost of moving to a new EHR.

There are a handful of innovative large institutions that unleashed great innovative momentum through aggressive piloting and partnership with third parties. The pattern of their innovation is similar – they make public a problem they are trying to solve, they make data available to support the solving of that problem and then they find a pathway to engaging technology innovators to solve the problem. Here are a handful of leading innovators:

1. The Office of Disease Prevention and Health Promotion. Under the guidance of Linda Harris, Director, Division of Health Communication and ehealth, Ellen Langhans, Program Manager of Health Communication and ehealth and Silje Lier, Communications Advisor of Health Communication and ehealth the ODPHP has not only engaged third party technology companies against the goals of ODPHP, but has also systematically shared their learnings with other government and public sector groups to advance best practices in patient literacy around preventive health. Their myfamily mobile program has been in pilot for the past ten months and is about to release version 2.0 which includes EHR integration and connectivity with the new Apple Healthkit platform build into iPhone software.
2. Boehringer-Ingelheim Pharmaceuticals under the guidance of Jon Doniger in their New Business Model group is aggressively engaging new technology companies to help his organization understand the role that pharma could be playing in health care delivery in 10 years.
3. Allscripts EHR platform under the leadership of Tina Love has embraced third party developers and platform "openness" to tap into the power of technology innovators passionate about health care.
4. Johnson and Johnson systematically defines problems, provides data and financial incentives to engage third parties to innovate against their hardest problems.
5. The Robert J Wood Hospital System, like J&J, programmatically engages outside tech companies.
6. Box, the digital storage and collaboration platform, under the guidance of Missy Krasner, works with leading health providers to facilitate the engagement of technology innovators.
7. CMS (Centers for Medicare and Medicaid Services) from an initial spark set off by Todd Park, CTO of the United States, is a voluminous publisher of health data. They have been followed quickly by the FDA and their openFDA initiative. What is remarkable about these two groups is their willingness to publish their data at a stage of "excellence", but not "perfection". CMS recently released a set of

> Medicare billing data that detailed what every provider in the US charged for every procedure. The data only can get people about 50% of the way to really making cost decisions around health care, but rather than bloat their data set, make it too complex for initial analysis, cover in fifty layers of disclaimer, or WAIT and release it when it's better, they made the data set public, put in place some tools for people who were not used to sets that big, clearly explained the origins and then let the data shark feeding frenzy ensue.

In summary, Lyfechannel believes that technology companies that partner with "large insiders" and lead with patient behavior vs. cool technology have the greatest opportunity to impact health outcomes in the next 10 years. There are some great innovators that should serve as a model, and no shortage of technology innovators with limitless energy and caffeine to try and impact population health.

Thank you again to the Chairpersons and members of the subcommittees for your time today and the opportunity to participate in this hearing. I would love to answer any questions you might have.

Mr. WALDEN. Thank you very much, Mr. Vockell. We appreciate your testimony as well.

And now we are going to go to Mr. Riskin. We appreciate your being here. And founder of Health Fidelity. Thank you for being here, Dan. And turn that microphone on, pull it close. And we look forward to your comments.

STATEMENT OF DAN RISKIN

Mr. RISKIN. Good morning, Chairman Walden, Chairman Pitts, Ranking Member Eshoo, Ranking Member Pallone and members of the subcommittees. It is an honor to testify.

I am a serial entrepreneur, founder of Health Fidelity, a leading big data analytics company, and consulting faculty at Stanford University School of Medicine. In addition, I am a practicing physician, board certified in surgery, critical care, palliative care, and clinical informatics. I serve on eHealth Initiative Leadership Council and collaborated with Bipartisan Policy Center on their efforts toward patient safety and healthcare IT.

I have been fortunate to succeed as an entrepreneur, educator and surgeon, and I am grateful to the Federal Government for contributing to my success. I have been awarded multiple grants from the NIH and National Science Foundation, each grant resulting in creation of multiple longstanding, long-term, high-paying skilled jobs. Every Federal dollar received has resulted in $15 of follow-on private sector investment. These efforts have led to companies and products used at Harvard, Stanford and other leading institutions to benefit patients and enhance medical knowledge. My background has afforded me unique insight into healthcare innovation and practice.

21st century technology in health care includes devices, data, information-enabled work flow. This newly emerging data-driven health care not only offers the right information at the right time for the right patient, but also provides a needed pathway for population health, analytics and patient engagement. The goal is a more efficient, effective and approachable healthcare system. Collaboration and innovation are required, and Government has a critical role to play.

Today I will focus on three actionable recommendations to promote safe and meaningful innovation in health care. These include re-defining interoperability to share the information that is needed for clinical analytics and population health; revising our approach to quality to better align with improved outcomes and reduced costs, and research to better understand safety and healthcare IT.

I recently cared for a very nice woman who was failed by our healthcare system. A heart murmur had been noted during physical exam years earlier. Unfortunately, on changing her insurance, the information was buried and lost in medical documentation. Her failing heart valve was only discovered years later when she presented to the emergency department unable to breathe. She required an emergency operation, leading to an extended ICU stay and millions of dollars at taxpayer expense. If her condition had been recognized early and treated electively, the likely costs would have been far lower, and she and her family would have been

spared a month-long stay in the hospital. I will discuss recommendations in the context of her case.

The first actionable recommendation is a better definition of interoperability. Current efforts and proposed regulations focus on sharing patient's summaries only. Unfortunately, there is simply not enough information in these summaries for innovative analytics companies like mine to promote data-driven health care. In this clinical case, an exam finding was documented in the physician narrative, but did not show up on the problem list and would not be present in an interoperable summary. To support interoperability of summaries only, as is proposed in current regulation is to ignore critically important information such as home environment, medication compliance, exam findings and hospital course. Innovation and care improvement will be hobbled for years to come by this arbitrary limitation.

Through the Meaningful Use program, our country has subsidized electronic capture of clinical data. Why wouldn't we require that all data we paid to capture be available for use by innovative companies and technologies to actually improve care.

The second actionable recommendation is an enhanced definition of quality. This patient's care met all process measures required, she had routine tests, documented counseling, weight documented, but did she receive great care? Quality measures and increasingly selected for feasibility, meaning we often select for what is easy to measure rather than what really influences outcomes. In this case, a relevant measure of quality would be whether the patient received appropriate follow-up for her heart murmur. If quality measures are our national target, this is the time to refine our approach and require accurate and meaningful quality measures in health care.

Finally, my patient's information was exposed to many healthcare software systems. Were these systems safe and effective? While the country defines a first-pass approach to healthcare IT safety, we must acknowledge these IT systems are new, innovative and rapidly evolving. To refine our regulatory approach over time, we will need information on how and when healthcare software is safe versus potentially dangerous. Supportive academic and clinical research in healthcare IT benefits and risks would go a long way to help us refine regulation over time.

We are going in the right direction. Health systems, payers and vendors are collaborating through new financing models and newly available data with new enthusiasm, but there is a great deal of work left to do if we are to bridge the gap from electronic information to better and more efficient care.

I look forward to continuing to work with you to leverage our national HIT investment to create data-driven health care. The U.S. is well poised to revolutionize health care and to benefit our people and economy at home while showing global leadership in this critical industry.

[The prepared statement of Mr. Riskin follows:]

Statement of
Dan Riskin
Founder, Health Fidelity
Consulting faculty, Stanford University

Before the
U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Communications & Technology
and
Subcommittee on Healthcare

Hearing on "21st Century Technology for 21st Century Cures"

July 17, 2014

Testimony of Dan Riskin

Committee on Energy and Commerce Subcommittee on Communications & Technology and Subcommittee on Healthcare

Summary

Good morning, Chairman Walden, Chairman Pitts, Ranking Member Eshoo, Ranking Member Pallone, and Members of the Subcommittees. It is an honor to testify.

I am a serial entrepreneur, Founder of Health Fidelity, a leading big data analytics company, and consulting faculty at Stanford University School of Medicine. In addition, I am a practicing physician, board certified in surgery, critical care, palliative care, and clinical informatics. I also serve on the eHealth Initiative Leadership Council and collaborated with Bipartisan Policy Center on their Oversight Framework for Assuring Patient Safety in Health Information Technology.

I have been fortunate to succeed as an entrepreneur, educator, and surgeon and I am grateful to the federal government for contributing to my success. I have been awarded and named principal investigator on multiple grants from the National Institutes of Health and National Science Foundation, each grant resulting in creation of multiple long-term high-paying skilled jobs. For every federal dollar received, I have secured at least $15 in follow-on private sector investment. These efforts have led to companies and products used at Harvard, Stanford, and other leading institutions to benefit patients and enhance

medical knowledge.

My background has afforded me unique insight into healthcare innovation in practice. Entrepreneurship in healthcare is difficult work and requires an ecosystem of expert talent, venture and strategic financing, broad-minded health systems, and engaged patients.

21st century technology in healthcare includes devices, data, and information-enabled workflow. This industry disruption is sometimes termed data-driven healthcare. Data-driven healthcare not only assures the right information is available for the right patient at the right time, but also provides pathways for information to be used in less traditional ways, such as population health and patient engagement.

The goal in data-driven care is not to capture healthcare data electronically or enhance reporting of information, though these are necessary steps along the way. The goal is rather a more efficient, effective, and approachable healthcare system that provides high quality care at an affordable price. Although great strides have been made, achieving our common goal will require collaboration and innovation from all involved parties. The government has a critical role to play.

Today, I will focus on three actionable recommendations to promote safe and meaningful innovation in healthcare. These include redefining interoperability to share the information that is needed for clinical analytics and population health, revising our

approach to quality to better align with improved outcomes and reduced costs, and research to better understand safety in healthcare IT.

I recently cared for a very nice woman who was failed by our healthcare system. A heart murmur had been noted during physical exam years earlier. Unfortunately, on changing her insurance, the information was buried and lost in medical documentation. Her failing heart valve was only discovered years later when she presented to the emergency department unable to breath. She required an emergency operation, leading to an extended ICU stay and millions of dollars of taxpayer expense. If her condition had been recognized early and treated electively, the likely cost would have been far lower and she and her family would have been spared a month-long stay in the hospital. I will discuss recommendations in the context of her case.

The first actionable recommendation is a better definition of interoperability. Current efforts and proposed regulations focus on sharing patient summaries. Unfortunately, there is simply not enough information in these summaries for innovative analytics companies to promote data-driven healthcare. In this clinical case, an exam finding was documented in a physician narrative, but did not show up on the problem list and would not be present in an interoperable summary. To support interoperability of summaries only, as is proposed in currently regulation, is to ignore critically important information such as home environment, medication compliance, exam findings, and hospital course. Innovation and care improvement will be hobbled for years to come by such an arbitrary limitation. Through the Meaningful Use program, our country has footed much of the

cost for electronic capture of clinical data. Why wouldn't we require that all the data we capture be available for use by innovative companies and technologies to improve care?

The second actionable recommendation is an enhanced definition of quality. This patient's care met all process measures required. She had routine tests, documented smoking cessation counseling, and weight documented and trended. But, did she receive great care? Quality measures are increasingly selected for feasibility, meaning we often select for what is easy to measure rather than what really influences outcome. In this case, a relevant measure of quality would have been whether the patient received appropriate clinical follow up for her heart murmur. These types of clinical measures are hard to measure and track, but foundational for good care. If quality measures are our national target, this is the time to refine our approach and require accurate and meaningful quality measures in healthcare.

Finally, my patient's information was exposed to many healthcare IT software systems. Were these systems safe and effective? While the country defines a first pass approach to healthcare IT safety, we must acknowledge that these IT systems are new, innovative, and rapidly evolving. Not only must we understand the efficacy of the technology, we must also ensure proper integration into clinical workflow. Technology creates a new way of providing care that should be based on real science, not trial and error. To refine our regulatory approach over time, we will need information on how and when healthcare IT is safe versus potentially dangerous. Support of academic and clinical research on healthcare IT benefits and risks would go a long way to help us refine regulation over

time.

We're going in the right direction. Health systems, payers, and vendors are collaborating over new financing models with newly available data and with new enthusiasm. Venture financing in healthcare is at its highest level since 2001 and growing. Innovation in healthcare is being rewarded with a robust acquisition and IPO market. But, there is a great deal of work left to do if we are to bridge the gap from electronic information to better and more efficient care. I look forward to continuing to work with you to leverage our national healthcare IT investment to create data-driven healthcare. The US is well poised to revolutionize healthcare to benefit our people and economy at home while showing global leadership in a critical industry.

Mr. WALDEN. Thank you very much, Mr. Riskin. We appreciate your testimony.

We will go now to Mr. Misener, vice president, Global Public Policy at Amazon. Paul, please go ahead. Thanks for being here.

STATEMENT OF PAUL MISENER

Mr. MISENER. Thank you, Chairman. Good morning, Chairman Walden, Chairman Pitts, and Ranking Members Eshoo and Pallone. My name is Paul Misener, and I am the vice president of Global Public Policy at Amazon.com. On behalf of Amazon and our customers, thank you for inviting me to testify today on how 21st century technology enables 21st century cures.

After briefly describing cloud computing technology, my testimony will illustrate how innovative healthcare organizations, both large and small, established and startup, public and private already use cloud computing to foster the innovation cycle of discovery, development and delivery of new biomedical treatments and cures. I will conclude by suggesting three ways that Congress could help accelerate this cycle by adopting policies to facilitate use of cloud computing for health care.

With cloud computing, information technology users, including healthcare enterprises now can acquire technology resources such as compute power and storage on an as-needed basis instead of buying, owning and maintaining their own data centers and servers.

In 2006, Amazon's cloud computing business, Amazon Web Services, or AWS, began offering developer customers access to in-the-cloud infrastructure services. AWS now has hundreds of thousands of customers, including over 3,000 academic institutions and 800 Government agencies.

In the healthcare sector, enterprises of all sizes and types are beginning to use cloud computing technology for the discovery of new biomedical treatment and cures. As the chairman mentioned earlier, in 2013, Novartis scientists discovered a large molecule involved in the disease mechanism for a particular type of cancer. The scientists wanted to virtually screen 10 million compounds against the large molecule. Such a large number of screenings is extremely computationally intensive. Novartis did not have the capacity in their existing data center to do this type of test, and building new infrastructure would have cost an estimated $40 million. Instead, using AWS, they built a virtual high performance computing center in the cloud and were able to perform the equivalent of 39 years of science in less than half a day and for under $5,000.

Enterprises are also beginning to use cloud computing for the development of new biomedical treatments and cures. For example, in the summer of 2012, Merck was noticing higher than usual discard rates for certain vaccines. The high discard rates could result from many factors. Evaluating these factors for every vaccine produced was extremely challenging using a traditional spreadsheet approach, so instead, Merck worked with a partner to implement a cloud-based solution using AWS, and over a 3-month period, they were able to combine all of their data sources and perform over 15 billion calculations and more than 5.5 million vaccine batch-to-

batch comparisons, and thus they were able to precisely identify how characteristics of fermentation had direct impact on vaccine discard rates.

Lastly, enterprises are beginning to use cloud computing for the delivery of new biomedical treatments and cures. For example, the USFDA, which receives 900,000 handwritten reports of adverse drug effects each year, needed a way to make the data entry process more efficient and reduce costs. Using AWS cloud computing, the FDA and Captricity quickly turned manual reports into machine readable information, reducing costs from $29 per page to $0.25 per page.

Chairman Walden and Chairman Pitts, please allow me to suggest three ways that Congress could help accelerate the innovation cycle of discovery, development and delivery of new biomedical treatments and cures by facilitating the use of cloud computing for health care. First, to help accelerate the discovery of new biomedical treatments and cures, Congress could work with NIH to establish and operate cloud-based data management platforms to which federally funded researchers could upload their research data along with any relevant software resources required to reproduce their analysis of the data. Other researchers in the field could then access the data in software in order to reproduce the results, re-analyze previously collected data in novel ways, or even automate the analysis of new data using the same approach as the original experiment.

Second, to accelerate the discovery and development of new biomedical treatments and cures, Congress could enact both H.R. 967 and H.R. 1232. These are bills that would assess and facilitate the use of cloud computing by Federal science agencies.

And third, to help accelerate the delivery of new biomedical treatments and cures, Congress could work with HHS to modernize implementation of HIPAA so that healthcare providers could readily employ the benefits of cloud computing. By narrowing the application of HIPAA to situations where cloud services providers have access to and knowledge of health information, time and money won't be wasted on contracts that are mostly inapplicable, and cloud services providers can more reasonably comply with HIPAA by focusing on areas where they actually have access and knowledge of health information.

Chairman Walden and Chairman Pitts, thank you again for holding today's hearing and for inviting me to testify. I look forward to your questions.

[The prepared statement of Mr. Misener follows:]

amazon.com

Testimony of

Paul Misener
Vice President for Global Public Policy, Amazon.com

Before the

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Communications and Technology
Subcommittee on Health

Hearing on

21st Century Technology for 21st Century Cures

July 17, 2014

Good morning, Chairman Walden and Chairman Pitts, Ranking Members Eshoo and Pallone, and Subcommittee Members, my name is Paul Misener, and I am Amazon.com's Vice President for Global Public Policy. On behalf of Amazon and our customers, thank you for inviting me to testify today on how 21st Century technology enables 21st Century cures. We are grateful to you, and to Chairman Upton and Representative DeGette, for exploring this important topic.

After briefly describing cloud computing technology, my testimony will illustrate how innovative healthcare organizations – large and small, established and start-up, public and private – already use cloud computing to foster the innovation cycle of discovery, development, and delivery of new biomedical treatments and cures. I will conclude by suggesting three ways that Congress could help accelerate this cycle by adopting policies to facilitate use of cloud computing for healthcare.

Amazon.com opened for business on the World Wide Web in July 1995 and seeks to be Earth's most customer-centric company. After over a decade of building and running web applications and

databases for our retail business, we realized that we had developed a core competency in operating massive scale computing technology infrastructure and datacenters. So, we set out to serve a new set of customers – including medical research institutions and healthcare providers – with a cloud computing business, which we named "Amazon Web Services."

With cloud computing, information technology (IT) users, including healthcare providers, research institutions, start-ups, and other enterprises, now can acquire technology resources such as compute power and storage on an as-needed basis, instead of buying, owning, and maintaining their own datacenters or servers. This is known as the "utility" model of obtaining and using IT capability, analogous with how enterprises obtain water, gas, or electrical power. Users only pay for what they use – by the compute-hour or storage-gigabyte – and they are not locked into long-term contracts. If a program is funded one year and then unfunded the next, or a pilot project or initial testing phase does not achieve the expected results, organizations no longer need to be tied to large, capital IT expenditures that can cost hundreds of thousands or even millions of dollars. As a result, healthcare start-ups, medical research institutions, hospitals, and clinical providers of all sizes have more agility, enabling biomedical innovations for 21st Century cures. In sum, cloud computing offers IT users, including healthcare enterprises, many benefits:

- First, with cloud, IT users can trade capital expenditures for variable expenses. That is, users can pay only for what IT they actually consume, and only when they consume it.
- Second, with cloud, those variable expenses are lower than they would be if the user self-provided IT services. With inherent economies of scale, the large-scale commercial cloud is simply more efficient than anything a particular user could build and operate for itself.
- Third, users don't need to guess their capacity needs. Before cloud, users risked the waste of buying too much IT capacity if demand were lower than guessed, or they risked dissatisfaction of their customers or citizens with shortages, if the users bought insufficient IT capacity to meet demand.

- Fourth, the speed and agility of user innovation is dramatically increased with cloud. Instead of waiting many weeks to obtain IT infrastructure, virtually unlimited capacity is available to users within minutes.

- Fifth, cloud computing allows a user's scarce technical talent to focus on its core mission, not on maintaining basic compute and storage infrastructure to support it. With the budget challenges that organizations face today, that focus is valuable now more than ever.

In 2006, Amazon's cloud computing business, Amazon Web Services, or "AWS," began offering developer customers access to in-the-cloud infrastructure services. AWS now has hundreds of thousands of customers, including over 3,000 academic institutions and 800 government agencies.

In the healthcare sector, enterprises of all sizes and types are beginning to use cloud computing technology for the *discovery* of new biomedical treatments and cures. Here are a few examples from our AWS experience:

- Spiral Genetics, a Seattle, Washington-based bioinformatics company formed in 2009, makes high-performance software that helps researchers analyze DNA in the cloud. Before Spiral Genetics was founded, the cost of sequencing a human genome was $100,000, the chemical process of sequencing took 30 days, and computational processing in traditional hardware-based infrastructure took several weeks. Since then, various sequencers have been developed that can analyze a human genome in one day for a few thousand dollars. Spiral Genetics can now process thousands of datasets simultaneously while complying with the strictest security requirements for its customers.

- Seven Bridges Genomics, a Cambridge, Massachusetts-based bioinformatics firm, offers researchers and labs a cloud platform for analyzing genetic data generated through next-generation sequencing (NGS) technologies. Through its "IGOR" platform, Seven Bridges provides a one-stop solution for managing NGS projects and enables customers to create and run complex data analysis pipelines easily using a drag-and-drop interface.

- In 2013, Novartis scientists discovered a large molecule involved in the disease mechanism of a particular type of cancer. The scientists wanted to virtually screen 10 million compounds against the large molecule. Such a large number of screenings is extremely computationally intensive. Novartis did not have capacity in their existing datacenter to do this type of test, and building new infrastructure would have cost an estimated $40 million dollars. Instead, they built a virtual high performance computing center in the cloud, and were able to perform the equivalent of 39 years of science in less than nine hours for a cost of $4,200. In the process, they identified three compounds that may be able to interact with the large molecule they were targeting.

- The number of genetic tests available to doctors and hospitals is constantly increasing, and they can be very expensive. Professor Peter Tonellato at Harvard Medical School's Laboratory for Personalized Medicine is interested in determining which tests will result in better patient care and better results. Using cloud computing technology to cost-effectively and securely analyze large amounts of human genomic data, Dr. Tonellato's laboratory is able to identify the tests, protocols, and trials that are worth pursuing aggressively for both FDA approval and clinical use.

- Funded by the National Institutes of Health (NIH), the Human Microbiome Project (HMP) is a collaborative effort, involving over 300 scientists from more than 80 organizations, to comprehensively characterize the microbial communities inhabiting the human body and elucidate their role in human health and disease. Large amounts of genetic information on the microbes that naturally colonize our bodies—enough information to fill more than 1,000 standard DVDs—are now available as a free dataset, enabling users to access and analyze the data online.

- The 1000 Genomes Project is an international research effort coordinated by a consortium of 75 companies and organizations to establish the most detailed catalogue of human genetic variation. The project dataset has grown to 200 terabytes of genomic information, including DNA sequenced from more than 1,700 people, that researchers can now access via cloud computing for use in disease research.

- Baylor University manages the Cohorts for Heart and Aging Research in Genomic Epidemiology (CHARGE) project. CHARGE is a collaboration of hundreds of scientists from around the world who are using data to research the causes and prevention of disease. Together with DNAnexus, Baylor scientists were able to sequence the DNA of more than 14,000 individuals (3,751 whole genomes and 10,771 whole exomes) and analyze over a petabyte of human genomic data in the largest-ever cloud-based analysis of genomic data.

- The High Performance Computing Facility of the New York University (NYU) Center for Health Informatics and Bioinformatics delivers forefront-computing capabilities to researchers at the NYU Langone Medical Center. The facility allows medical informatics and bioinformatics researchers to accelerate discovery and innovation through access to computational power, data storage, supercomputing resources and data sharing with collaborators throughout the world. By using the cloud, the HPC facility expanded the set of services it can offer to NYU researchers, who can now access the resources they need, when they need them. The cloud also helps researchers collaborate so that they easily share their findings and datasets with researchers around the world.

- The Global Alliance for Genomics and Health is an organization formed to help accelerate the potential of genomic medicine to advance human health. It brings together over 190 leading institutions working in healthcare, research, disease advocacy, life science, and information technology. The partners in the Global Alliance are working together to create a common framework of harmonized approaches to enable the responsible, voluntary, and secure sharing of genomic and clinical data.

- The Icahn School of Medicine at Mount Sinai uses StationX GenePool to mine The Cancer Genome Atlas (TCGA) in order to better understand the genetic component of breast and ovarian cancers. TCGA is a comprehensive and coordinated effort to accelerate our understanding of the molecular basis of cancer through the application of genome analysis technologies, including large-scale genome sequencing. TCGA is a joint effort of the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI), two of the 27 Institutes and Centers of the National Institutes of Health.

- The National Database for Autism Research (NDAR) is an extensible, scalable informatics platform for Autism Spectrum Disorder (ASD) relevant data at all levels of biological and behavioral organization (molecules, genes, neural tissue, behavioral, social and environmental interactions) and for all data types (text, numeric, image, time series, etc.). NDAR was developed to share data across the entire ASD field and to facilitate collaboration across laboratories. Cloud-based hosting of this research data is enabling autism researchers to increase collaboration and the sharing of data across federally-funded studies.

Enterprises of all sizes and types also are beginning to use cloud computing for the *development* of new biomedical treatments and cures. Here are a few examples from our AWS experience:

- Illumina is a San Diego, California-based company that manufactures lab instruments for genetic sequencing. Genetic data produced in the lab requires significant analysis before meaningful information can be produced, such as comparing the raw data produced by the instruments to libraries of genetic anomalies. As the amount of genetic information being produced began to grow, Illumina realized that data storage and processing was a major bottleneck for biologists using their products. Illumina created the IT platform BaseSpace to help address this problem. Previously, researchers who did not have the on-site computational expertise to analyze these datasets would often have to store them on disks and send them in the mail for analysis. Using BaseSpace, they have the analysis performed in the cloud using as much compute power as necessary. This also helps facilitate collaboration between different sites by allowing remote collaborators to log in to BaseSpace and contribute data to a trial or receive data.

- In the summer of 2012, Merck was noticing higher-than-usual discard rates for certain vaccines. Excessive discard rates can lead to disruptions in supply of the vaccines for patients and healthcare providers. However, given the sensitive nature of the manufacturing and storage processes, the high discard rates could result from many factors, including process errors, plant equipment errors, or building environmental controls. Evaluating these factors for every vaccine produced was extremely challenging using a traditional "spreadsheet" approach, so instead Merck worked with a partner to implement a cloud-based solution. Over a three month period, they were able to combine all of their data sources and perform over 15 billion calculations and more than 5.5 million vaccine batch-to-batch comparisons. They were able to identify, quantitatively, that certain characteristics in a fermentation step had a direct impact on

the vaccine discard rate. They were then able to use this information to propose changes in their manufacturing process which could then be tested in the lab.

- Siemens Healthcare Diagnostics is a leading global manufacturer of diagnostic instruments and tests for clinical labs. Over the past several years, Siemens has been partnering with pharmaceutical companies to develop a type of personalized medicine known as Companion Diagnostics, where a diagnostic test is used to help determine whether a particular pharmaceutical treatment will be effective for a particular patient. Siemens has recently developed a new cloud-based Companion Diagnostics analytical platform with applications that typically involve merging genomic analysis with other patient data to determine if a particular drug would be effective. This would be extremely challenging to deliver to a typical clinical lab without drawing on cloud computing to perform the data analysis.

Lastly, enterprises of all sizes and types are beginning to use cloud computing for the *delivery* of new biomedical treatments and cures. Here are a few examples from our AWS experience:

- Health Guru is a New York City company that provides online health information videos, such as instructional videos on how to look for signs of a heart attack and how to manage diabetes through diet. Founded in 2006, Health Guru now has a cloud-based library of more than 3,500 videos and more than one billion cumulative streams on Healthguru.com. Health Guru also developed a video syndication technology so that its partners can access the video library for their own websites and be able to use Health Guru products and services to manage content.

- The Schumacher Group is a physician practice management company based in Lafayette, Louisiana that supports healthcare providers in over two dozen states. They adopted cloud computing in a number of areas of their business in order to be more nimble and provide better services to their customers and their patients. Some of the services they are now migrating to the cloud include aspects of their business intelligence system and data archiving. Adoption of the cloud has already led to quicker response times and decreased costs: in one example, they were able to save three months of time and $75,000 on a critical project.

- The U.S. Food and Drug Administration (FDA), which receives 900,000 handwritten reports of adverse drug effects each year, needed a way to make the data entry process more efficient and reduce costs. Using cloud computing, the FDA and Captricity quickly turn manual reports into machine-readable information with 99.7 percent accuracy, reducing costs from 29 dollars per page to 25 cents per page.

- Ideomed has developed innovative mobile health applications focused on managing patients with severe chronic diseases. Ideomed was asked by Spectrum Health, a non-profit Healthcare network in West Michigan, to create a custom healthcare portal. The portal allows patients to track relevant health-related activities, such as whether the patient took their medication or adhered to a recommended exercise regime. Patients are able to provide information via the

web or mobile devices. The information is then transmitted to the patient's physician so he or she can monitor the patient's progress. Ideomed's platform continues to evolve as they add new capabilities, support for new diseases and, by using cloud services, they were able to react quickly to the demands of patients and physicians, while controlling the total cost to Spectrum.

- The U.S. Center for Disease Control and Prevention (CDC) is responsible for providing awareness for all health-related threats and to support responses to these threats at the national, state, and local level. With CDC's cloud-based BioSense 2.0 program, health officials can exchange information faster, improve their common awareness of health threats over time and across regional and national boundaries, and better coordinate investigations and community actions to protect health.

Chairman Walden and Chairman Pitts, please allow me to suggest three ways that Congress could help accelerate the innovation cycle of discovery, development, and delivery of new biomedical treatments and cures by facilitating the use of cloud computing for healthcare.

First, to help accelerate the *discovery* of new biomedical treatments and cures, Congress could work with NIH to establish and operate cloud-based data management platforms, which federally-funded researchers could use to share their data. Such federally-funded researchers currently are required to share their data openly or make it accessible to others in their field of research. However, researchers are left on their own to fund, develop, and operate data sharing platforms and, as a result, research projects that cost hundreds of thousands (or even millions) of dollars to collect experimental data are forced to discard the data after publication. The only lasting remnant of the data may be a visual graph or written description of the data in a published paper. In some cases, data are forever lost or can only be recreated with investments similar to the cost of the original experiment.

If federal funding agencies, such as NIH, established and operated cloud-based data management platforms, federally-funded researchers would simply upload their research data along with any relevant software resources required to reproduce their analysis of the data. Other researchers in the field could then access the data and software in order to reproduce results, re-

analyze previously collected data in novel ways, or even automate the analysis of new data using the same approach as the original experiment. This would result in the elimination of costly and unnecessary duplicative research and thereby accelerate the pace of biomedical discovery.

Second, to accelerate the *discovery* and *development* of new biomedical treatments and cures, Congress could enact both H.R. 967, the Advancing America's Networking and Information Technology Research and Development Act (which would require an assessment of how federal science agencies can facilitate the use of cloud computing for federally-funded science and engineering research), and H.R. 1232, the Federal IT Acquisition and Reform Act (which would assist federal agencies with healthcare, research, and scientific missions to improve their technology capabilities and efficiency).

Third, to help accelerate the *delivery* of new biomedical treatments and cures, Congress could work with the Department of Health and Human Services (HHS) to modernize implementation of the Health Insurance Portability and Accountability Act (HIPAA) so that healthcare providers can readily employ the benefits of cloud computing without any compromise of the strong privacy protections HIPAA now affords health information. To date, HHS has indicated that a cloud computing services provider that stores information for a healthcare provider also is subject to HIPAA as a "business associate," even when the stored information is encrypted and the cloud services provider lacks the decryption key, and regardless of whether the cloud services provider agreed to do so or had otherwise received notice of the health information. This interpretation impedes healthcare delivery entities from leveraging cloud services by causing the parties to negotiate a "business associate agreement" in which virtually all of the terms are inapplicable because the cloud services provider does not have access to health information. By narrowing the application of HIPAA to situations where a cloud provider has access to, and knowledge of, the information, parties can avoid wasting money on contracts that are

mostly inapplicable, and cloud services providers can more reasonably comply with HIPAA by focusing on areas where they have access and knowledge of health information.

Chairman Walden and Chairman Pitts, thank you again for holding today's hearing and inviting me to testify. I look forward to your questions.

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Mr. WALDEN. Those are wonderful recommendations. Thanks for your testimony. It is always impressive to see what is happening out there.

For the members' benefit, we have about 10 minutes to go in the first vote, but we always know that takes a little longer, so we will try and get through the witnesses if we can.

We will go now to Mr. Robert Jarrin, Senior Director, Government Affairs, Qualcomm Incorporated. Thank you for being here. We look forward to your testimony.

STATEMENT OF ROBERT JARRIN

Mr. JARRIN. Thank you, Chairman. Good morning, Chairman Walden and Chairman Pitts, Ranking Members Eshoo and Pallone, and members of the subcommittees. On behalf of Qualcomm, an American company and the world's largest wireless chipset supplier and largest licensor of mobile technology, it is an honor to be here again. Thank you for inviting me.

Mobile technology, Qualcomm's specialty, has become the largest communications platform in the history of the world, and it continues to grow. Currently, there are 355 million connections in the U.S. and over 7 billion globally.

We forget how quickly mobile technology has proliferated. The Android OS and Apple's iPhone were launched in 2007, the iPad in 2010. You wouldn't know it, the way consumers rely upon these services and devices. Qualcomm can't make this happen by itself, which is why we work with many partners. I am pleased to be here today with one of them, Amazon.com. Their leading-edge Kindle Fire HDX tablet, Fire smartphone and Fire TV media player all incorporate Qualcomm's innovative Snapdragon chipsets.

Qualcomm's technologies are found in products that touch every aspect of society, including health care, which is why in 2011, we launched Qualcomm Life, a wholly owned subsidiary focused on medical device connectivity and management of health data. At Qualcomm, we understand that nothing can transform a sector like mobile 3G and 4G technologies. Health care is a good example, one in which I have personal experience.

On August 16th, 2006, my mother was diagnosed with Stage III–C late term ovarian cancer. She was 65, a widow, with limited English proficiency. From the start of her odyssey, I discovered that doctors, clinics and hospitals were not sharing her healthcare information. I was struck by the lack of continuity of care. When she left the care provider or facility, there was no mechanism to remotely monitor her basic physiological status. This seemed dangerous in light of countless doses of chemotherapy, protein inhibitors, and toxic serums she endured, which caused horrible side-effects, including extreme high blood pressure and edema.

In the years since my mom's initial diagnosis, mobile computing devices have helped personalize health care. Remote patient monitoring is now helping drive systemic changes in healthcare networks. Platforms, such as Qualcomm Life's HealthyCircles, facilitate the management and sharing of medical information between stakeholders across the patient's healthcare community.

Qualcomm Life and its partners produce novel commercially available 21st century mobile medical solutions, such as mobile

ECG recorders, wireless telemetry sensors, mobile glucose monitors, software systems that deliver live patient data to a doctor's smartphone, smart inhalers, and radiological imaging viewers for mobile devices, and implantable pulmonary sensors that communicate wirelessly with bedside monitors.

The future is even more exciting. The X PRIZE Foundation and Qualcomm developed a $10 million competition, the Qualcomm Tricorder X PRIZE, to produce a device that diagnose 15 distinct diseases in a group of 15 to 30 people within 3 days by a consumer, independently of a healthcare worker or facility.

If investments are any sign of the future, the first half of this year shows 143 companies having raised $2.3 billion year to date, thus eclipsing the 2013 total of $2 billion. Those investments include some by the Qualcomm Life Fund, which was formed in 2011 and is now considered one of the most prolific investors in wireless health.

However, challenges do persist. Lack of reimbursement is a major barrier to telehealth and remote patient monitoring technologies. Medicare telehealth provisions in the Social Security Act are overly restrictive and exclude the majority of these technological innovations, and that needs to be changed. Another is the Center for Medicare and Medicaid Services EHR incentive payment program, popularly referred to Meaningful Use rules, which do not include the ability to upload patient-generated health data into certified EHRs. Future stages of the program should specify the incorporation of patient-generated health data from home use medical devices into EHRs.

Another important issue is spectrum, the lifeblood of our wireless networks. Qualcomm commends this committee and Congress for all the work it is doing to make additional mobile broadband spectrum available. This work is critically important.

In closing, the speed of innovation should never come at the expense of patient safety. Health IT software and mobile medical apps developers should support data collection and quality mechanisms to foster patient safety and create a learning environment.

Nearly 8 years after my mom's diagnosis, I am thankful to her healthcare team that she is continuing to live an enjoyable life. I am also grateful for the advancements in 21st century medical technologies are helping society as a whole. Qualcomm has played a significant role in mobilizing health care, to improve lives and advance digital medicine, and it will continue to do so.

Thank you. I look forward to your questions.

[The prepared statement of Mr. Jarrin follows:]

Statement of
Robert Jarrin
Senior Director, Government Affairs
Qualcomm Incorporated

Before the
U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health
Subcommittee on Communications & Technology

Hearing on "21st Century Technology for 21st Century Cures"

July 17, 2014

Summary

Mobile technology continues to be the largest platform in history. With a global population of approximately 7.1 billion people, there are now over 7 billion mobile connections — 4.4 billion of which are unique. In the U.S. alone, there are 355 million mobile connections for a population of just over 317 million. The Centers for Disease Control (CDC) recently reported that the percentage of U.S. households that do not have a landline phone and rely only on a mobile phone has risen to 41 percent.

Qualcomm, an American company is the world's largest supplier of chips for wireless devices and the world's largest licensor of mobile technology. Sophisticated mobile computing devices have helped underpin consumer health IT technologies, software and mobile medical and wellness apps. Remote patient monitoring is rapidly proliferating. Interoperability and data integration are starting to take hold.

Qualcomm's subsidiary Qualcomm Life and its partners produce some of the most novel 21st century mobile medical solutions that are commercially available: mobile ECG recorders, hospital grade wireless telemetry sensors, mobile blood glucose monitors for diabetics, medical software systems that deliver live patient data to a doctor's smartphone or tablet, wireless medical sensors for use with inhalers, software to make radiological imaging viewers available for mobile devices, wireless blood pressure cuff monitors, implantable pulmonary sensors that communicate wirelessly with bedside monitors, Wi-Fi enabled medical grade weight scales, and medical device data systems.

Investments in the mobile health space for the first half of this year show that approximately 143 companies have successfully raised $2.3B in 2014 YTD, which eclipses the 2013 total of around $2B. Those investments include some by the Qualcomm Life Fund which was formed in 2011 and has consistently ranked as one of the most prolific investors in the wireless health space.

Challenges to adoption persist. Lack of reimbursement payment coverage is a major barrier to telehealth and remote patient monitoring technologies. Current Medicare telehealth reimbursement provisions in the Social Security Act are outdated inhibitors to the proliferation of mobile health. They are limiting patient access to new technologies, effectively discouraging providers from utilizing advanced information communications in their practices.

Another challenge has been the lack of references to remote patient monitoring technologies and patient generated health data (PGHD) as criteria in the Centers for Medicare and Medicaid Services EHR incentive payment program, popularly referred to as the "Meaningful Use" rules.

Meaningful use has focused on Certified EHRs, EHR modules, and EHR systems, but has yet to fully encourage the involvement of patients and families in their care. The ability to upload PGHD into certified EHRs should be included in future stages of meaningful use as criteria to incentivize eligible providers to embrace the use of remote monitoring technologies.

Another important component of any 21st Century technology for 21st Century cures is spectrum, the life blood of our wireless networks. Spectrum is a finite natural resource which is rapidly being constrained. Qualcomm commends this Committee and Congress for its work to make available additional mobile broadband spectrum.

The speed of innovation should never come at the expense of patient safety. As innovative and essential products race to market, quality assurance processes and methodologies, including verification and validation found in rigorous quality and design controls should be implemented. Health IT software products and mobile medical apps should naturally be supported by data collection mechanisms to foster a true patient safety and quality learning environment.

Good morning, Chairman Walden and Chairman Pitts, Ranking Members Eshoo and Pallone, and Members of the Subcommittees. On behalf of Qualcomm, an American company that is the world's largest supplier of chips for wireless devices and the world's largest licensor of mobile technology, it is an honor to be here before you today – thank you for inviting me to testify.

Mobile technology, Qualcomm's specialty, has become the largest communications platform in the history of the world. With a global population of approximately 7.1 billion people, there are now over 7 billion mobile connections — 4.4 billion of which are unique.[1] In the United States alone, there are 355 million mobile connections for a population of just over 317 million.[2] A Pew Research report states that the national adoption rate for smartphones is 55 percent,[3] and the Centers for Disease Control (CDC) recently reported that 41 percent of U.S. households do not have a landline phone and rely exclusively on a mobile phone. Meanwhile, the CDC also found that of consumers who only use a mobile phone, just over 63 percent describe their health status as excellent or very good. Qualcomm believes it is crucial, indeed essential, that this enormous mobile technology platform be used to improve healthcare, and we are working on this in many ways.

It's easy to overlook how quickly mobile technology and smart devices have proliferated. For example, the Android operating system, so common today, was officially launched in 2007. Apple's iPhone and iPad were introduced in 2007 and 2010, respectively.[4] One would not know

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[1] *See* Wireless Intelligence, (Jan. 2013); *see also* U.S. Census Bureau Population Clock http://www.census.gov/main/www/popclock.html; GSMA Intelligence, Apr. 2014.
[2] See https://gsmaintelligence.com/session/log-in/?return_url=%2Fmetrics%2F3%2F0%2Fdata%2F%3Freport%3D53e409e13c017.
[3] *See* http://www.pewinternet.org/2014/04/03/usage-and-adoption/.
[4] *See* "iPhone introduced June 29 2007"

that considering how consumers rely on these devices and the technologies they incorporate for many things, including healthcare. Thus, it is not at all surprising that U.S. users of 4G LTE services already consume considerably more data than users of 3G technologies.[5] Wireless data usage has been doubling annually over the past several years, and if this trend continues for the next ten years, the level of usage will be more than 1000 times today's level. Given this extraordinary growth trend, Qualcomm has set a corporate goal to meet what we call the "1000x Challenge" — to support this growth by expanding the wireless capacity of today's mobile broadband networks 1000 fold. 3G and 4G technologies have literally helped to transform the way we transact in commerce, conduct public safety, learn, play sports, and most notably, deliver and personalize healthcare.

Qualcomm cannot make this happen by itself. One of our core values at Qualcomm is to work with partners—a wide variety of companies throughout the many facets of the ever-expanding wireless eco-system. In fact I am pleased to be joined at the witness table today by one of our technology partners, Amazon.com. Their leading edge Kindle Fire HDX Tablets, recently released Fire Smartphone, and innovative Fire TV media player all take full advantage of Qualcomm's innovative Snapdragon chipsets.

Let me turn to Qualcomm's health-related initiatives. In 2011 Qualcomm launched Qualcomm Life, Inc., a wholly owned subsidiary, with a goal to improve lives and advance the capabilities of wireless medical devices. Qualcomm Life is focused on medical device

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https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&es_th=1&ie=UTF-8#q=iphone%20introduced&safe=off; *See* "iPad introduced April 3, 2010" https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&es_th=1&ie=UTF-8#q=ipad+introduced&safe=off.

[5] *See* Sue Marek, "Study: U.S. LTE subscribers use about 1.6 GB of data per month," FierceWireless (June 23, 2014) *available at* http://www.fiercewireless.com/story/study-us-lte-subscribers-use-about-16-gb-data-month/2014-06-23 ("U.S. subscribers … are among the heaviest users of mobile data [and] LTE subscribers use dramatically more data than 3G subscribers.").

connectivity and data management, empowering medical device manufacturers to deliver wireless medical data quickly and easily to those who need it. Mobile computing platforms are ideal for improving healthcare.

Qualcomm Life's 2net™ Platform, is a unique, cloud-based solution that enables the wireless transfer, storage and display of medical device data. The platform is designed to be interoperable with different medical devices and applications, providing end-to-end wireless connectivity. The 2net Hub, one of many gateways used to access the 2net Platform's data center, houses a short-range radio that provides security, interoperability and seamless data transfer, while serving as the information highway for machine-to-machine (M2M) connectivity for medical devices into and out of the home.

2net Mobile is a software module that enables mobile computing devices such as mobile phones and tablets to serve as gateways to the cloud-based 2net Platform. The solution enables a mobile phone or tablet to collect and visualize data from medical devices and biometric sensors and securely transmit that information via the mobile phone or tablet's wireless wide area network (WWAN) cellular connection or Wi-Fi to the 2net Platform's data center. As mobile broadband-enabled smartphones, tablets, and laptops are becoming an extension of the person they belong to, products such as 2net Mobile are but one of the many applications that are available to the end user. We are rapidly approaching a day when everyone and everything in our world will be connected through seamless, ubiquitous wireless technologies.

There is no better example of how mobile technologies can transform a sector than by looking at the way patient engagement in healthcare also has changed throughout the past eight years. On August 16, 2006, my mother was diagnosed with Stage III-C late term ovarian cancer.

At the time, she was 65 and a widow with limited English proficiency attempting to navigate the U.S. medical system.

Early in my mom's odyssey, a number of frustrating challenges with her healthcare emerged. It quickly became clear that her doctors, clinics, and hospitals were not collaboratively sharing her healthcare information in any way, shape, or form. I foolishly thought that every healthcare encounter she had would be digitally documented in some kind of a shared healthcare data service that pooled her information and made it available for anyone on her care team. I assumed her tests, images, medications, and clinical interventions were freely available to her, the doctors or whomever else she chose. This was not the case.

I was particularly struck by the lack in continuity of care. When she left a doctor's office, hospital or clinic, there was no mechanism to remotely monitor her basic physiological parameters. The inability to remotely monitor her care was particularly dangerous in light of countless doses of chemotherapy, protein inhibitors, and toxic serums, with various side effects ranging from chronic high blood pressure to edema. There are over 117 million adults in the U.S., (not including children) suffering from at least one chronic illness in this same situation.[6]

In the eight years since my mom's initial diagnosis, sophisticated mobile computing devices have helped enable consumer health IT technologies, software and mobile medical and wellness apps. Remote patient monitoring is now rapidly proliferating through the use of medical devices and health IT software platforms that are beginning to drive systemic change within healthcare institutions and health networks. Today, solutions such as Qualcomm's Life's HealthyCircles™ and 2net ™ platforms facilitate the seamless and secure data capture, case

[6] *See* http://www.cdc.gov/chronicdisease/overview/index.htm.

management, and patient-centered care coordination by and between any stakeholder across a patient's care team, including healthcare professionals, patients, and their families. These platforms are ideally suited to enable scalable and cost-effective approaches for healthcare professionals to succeed with the latest CMS innovations such as Transitional Care Management (TCM) and the proposed Chronic Care Management (CCM) programs. Interoperability and data integration are starting to take hold for data exchange between platforms and electronic health records, clinical practice systems, hospital and lab records, and claims and medication history made more easily available for whoever needs it via mobile computing platforms.

In fact, Qualcomm Life and its partners produce some of the most novel 21st century mobile medical solutions that are commercially available, such as mobile ECG recorders for broad analytics, advanced hospital grade wireless telemetry sensors, mobile blood glucose monitors for diabetics, medical software systems that deliver live patient data to a doctor's smartphone or tablet, wireless medical sensors for use with inhalers, software to make radiological imaging viewers available for mobile devices, wireless blood pressure cuff monitors, implantable pulmonary sensors that communicate wirelessly with bedside monitors, Wi-Fi enabled medical grade weight scales, and medical device data systems that transmit, store, convert and display medical device data. These are not far-fetched scientific prophecies, but a short inventory of the types of medical technologies that exist and are readily available today.

What the future holds is even more exciting. People are beginning to engage more directly and effectively with providers. Diagnostic medical devices and sensors are being packed with wireless functionality and ever-increasing computing power to seamlessly track a patient's health state.

With this vision for the future in mind, the X PRIZE Foundation and Qualcomm developed a competition, the Qualcomm Tricorder X PRIZE, to spur radical innovation in personal healthcare technology. Qualcomm's Tricorder X PRIZE is a $10 million global competition to stimulate innovation and integration of precision diagnostic technologies, to ultimately help consumers make their own reliable health diagnoses virtually anywhere, at anytime. Qualcomm's Tricorder X PRIZE seeks the development of a portable, wireless device that monitors and diagnoses one's health conditions to allow unprecedented access to personal health metrics. The competition is set to conclude in January 2016, when we hope that the winning solution will be a wireless medical device that can check for anemia, urinary tract infection, type 2 diabetes, atrial fibrillation, stroke, obstructive sleep apnea, tuberculosis, COPD, pneumonia, ear infection, leukocytosis, hepatitis A, and other conditions and vital signs.

In the same vein, investments in the mobile health space are rapidly accelerating. Data for the first half of this year show that approximately 143 companies have successfully raised $2.3B in 2014 YTD, which already eclipses the 2013 total of around $2B. The funding is helping to seed six general categories of healthcare, including payer administration, digital medical devices, healthcare consumer engagement, population health management, personalized medicine, analytics and big data.[7] Qualcomm began making strategic investments in early-stage high-technology ventures in the wireless health space in 2007. In 2011, the Qualcomm Life Fund was formed with the mission of accelerating global wireless health services and technology adoption. The Qualcomm Life Fund specifically focuses on investing in venture-backed wireless health start-ups that will help accelerate the 2net Platform commercialization. The areas of specific interest to the fund range from personal wellness to disease management in areas such as: body worn or implantable biosensors or devices for vertically focused applications such as

[7] *See* http://rockhealth.com/2014/06/2014-midyear-digital-health-funding-update/.

chronic disease care, medication adherence, and fitness or wellness; integrated system providers that do remote diagnosis, monitoring or specialize in independent living; mobile software health IT applications; and health informatics/analytics.

Challenges to mobile health adoption do persist. In comments provided to this Committee, the American Telemedicine Association (ATA) cited the lack of payment coverage as a major barrier to the proliferation of telehealth and remote patient monitoring technologies.[8] For over a decade, ATA and its vast membership of industry leaders have argued that current Medicare telehealth provisions in the Social Security Act 1834(m) are overly restrictive and exclude the majority of technological innovations due to outdated and narrow definitions.[9] A 2012 report by a public-private task force on mHealth consisting of federal officials, academia, industry and other stakeholders, named outdated reimbursement regulations and policies as inhibitors to the proliferation of mobile health technologies. More recently, the Telecommunications Industry Association (TIA) sent a multi-stakeholder letter to the Secretary of Health and Human Services stating that the arduous reimbursement restrictions on telehealth services are limiting patient access to new technologies, effectively discouraging providers from utilizing advanced information communications technologies and solutions in their practices.[10] In fact, over the course of this Committee's 21st Century Cures hearings and roundtables, several witnesses and panelists have echoed the sentiment that the biggest obstacle to health IT

[8] *See* http://www.americantelemed.org/docs/default-source/policy/american-telemedicine-assn-for-e-c-health.pdf?sfvrsn=4.
[9] *See* 42 CFR § 410.78.
[10] *See* http://www.tiaonline.org/sites/default/files/pages/Multi-Assn%20Letter%20-%201834%28m%29%20%26%20MSSP%20ACOs%20060914.pdf .

innovation is the issue of reimbursement and the need to improve upon those outdated coverage regulations.[11]

Another challenge has been the lack of references to remote patient monitoring technologies and patient generated health data (PGHD) as criteria in the Centers for Medicare and Medicaid Services EHR incentive payment program, popularly referred to as the "Meaningful Use" rules. To date, meaningful use has focused on Certified EHRs, EHR modules, and EHR systems, but has yet to fully encourage the involvement of patients and families in their care. Remote patient monitoring technologies such as telemedicine, telehealth and mobile health are increasingly playing a vital role capturing PGHD. The ability to upload PGHD into certified EHRs should be included in future stages of meaningful use as criteria to incentivize eligible providers to embrace the use of remote monitoring technologies. Doing so would promote those capabilities to patients and families, particularly the most chronically ill who can be monitored in their homes and outside of healthcare institutions.

Another important component of any 21st Century technology for 21st Century cures is spectrum, which is the life blood of our wireless networks. Mobile health solutions are part and parcel of the enormous surge in wireless data usage, which is causing the spectrum crunch we are all now facing. Qualcomm commends this Committee and Congress for the work it is doing to unleash additional mobile broadband spectrum, which will be needed to support mobile medical applications and the growing number of new uses and users over the coming years.

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[11] *See* 21st Century Cures: The President's Council of Advisors on Science and Technology (PCAST) Report on Drug Innovation, May 20, 2014, http://energycommerce.house.gov/hearing/21st-century-cures-president%E2%80%99s-council-advisors-science-and-technology-pcast-report-drug; 21st Century Cures Roundtable: Digital Health Care, June 24, 2014, http://energycommerce.house.gov/event/21st-century-cures-roundtable-digital-health-care.

In closing, the speed of innovation should never come at the expense of patient safety. As innovative and essential products race to market, quality assurance processes and methodologies, including verification and validation found in rigorous quality and design controls should be implemented. Health IT software products and mobile medical apps should naturally be supported by data collection mechanisms to foster a true patient safety and quality learning environment.

Nearly eight years after my mother's initial diagnosis, I'm thankful to her healthcare team that she's continuing to live an enjoyable life. I'm also grateful for the advancements in 21st century medical technologies which are helping society as a whole. Qualcomm is playing a significant role mobilizing healthcare to improve lives and help advance digital medicine.

Thank you, I look forward to your questions.

About Qualcomm

Qualcomm Incorporated is the number one global supplier of wireless chips, and the leading inventor of wireless technologies. To date, Qualcomm has shipped over 15 billion chips. Qualcomm is a world leader in 3G, 4G and next-generation wireless technologies. If a person is using a 3G or 4G device today, Qualcomm's technology and ingenuity is being used.

Qualcomm Life (QCL), a wholly-owned subsidiary of Qualcomm Incorporated, is a medical device manufacturer focused on producing medical device data systems. QCL has developed the 2net™ Hub and 2net™ Platform. The 2net Hub, connects medical devices to the 2net Platform's data center and is a compact "plug-and-play" mobile broadband gateway that supports Bluetooth, Bluetooth Low Energy, Wi-Fi, and ANT+ local area radio protocols. The 2net™ Platform reliably captures and delivers medical device data to integrated portals or databases.

The Qualcomm Life Fund was established in 2011 with the amount of $100 million of funding with the goal of accelerating global wireless health services and technology adoption. The Qualcomm Life Fund specifically focuses on investing in venture-backed wireless health start-ups that will help accelerate the 2net™ Platform commercialization.

The Qualcomm Foundation, which Qualcomm established in 2010, is dedicated to developing and strengthening communities worldwide. Specifically, the Qualcomm Foundation focuses it philanthropic efforts on helping create and sustain educated, healthy, culturally vibrant

communities in regions around the globe. As sponsor of the Qualcomm Tricorder X PRIZE competition, the Qualcomm Foundation is proud to support the discovery of innovative mobile solutions that will contribute to the advancement of healthcare and diagnostics.

Qualcomm's Wireless Reach initiative is a strategic program that brings wireless technology to underserved communities globally. Wireless Reach invests in projects that foster entrepreneurship, aid in public safety, enrich teaching and learning, improve environmental sustainability and enhance the delivery of healthcare. Wireless Reach has 100 projects in various stages of development in 35 countries (many of which are related specifically to healthcare).

Qualcomm includes Qualcomm's licensing business, QTL, and the vast majority of its patent portfolio. Qualcomm Technologies, Inc., a wholly-owned subsidiary of Qualcomm Incorporated, operates, along with its subsidiaries, substantially all of Qualcomm's engineering, research and development functions, and substantially all of its products and services businesses, including its semiconductor business, QMC.

Global Employee Health Services, GEHS, is a department at Qualcomm with a mission to support the health of our employees and our business. Our vision is a healthy global community of Qualcomm employees engaged in engineering their health and healthcare for all. GEHS achieves its mission by providing a variety of health services to Qualcomm employees. Some examples include: clinical services from a premier onsite health center in San Diego, workplace health promotion programs that include health education activities and biometric health screening, employee activity challenges incorporating mobile technology, Global Health

Observances Celebrations like World Health Day and World Diabetes Day, and vaccination campaigns.

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Mr. WALDEN. Mr. Jarrin, thank you. And that is good news on your mother. Having lost a mother to ovarian cancer, I know how awful that——

Mr. JARRIN. I am sorry to hear that.

Mr. WALDEN [continuing]. Diagnosis is and the treatments can be. So I am glad to hear your mother is doing well.

We will now go to Dr. Jonathan Niloff, Chief Medical Officer and Vice President, McKesson Connected Care & Analytics, McKesson Corporation.

And for our members, the Whip's office will keep the vote open until we get there, so we can conclude with our final witness this morning.

So Mr. Niloff, thank you.

STATEMENT OF JONATHAN M. NILOFF

Mr. NILOFF. Thank you. Good morning, Chairman Walden and Pitts, Ranking Members Pallone and Eshoo, and distinguished members of the subcommittees. I appreciate the opportunity to appear before you today.

Throughout my career as a gynecologic oncologist in Boston, faculty member at Harvard Medical School, and founder of a small health IT company, I have seen firsthand the power of IT to improve outcomes, reduce costs, and accelerate the pace of change in our healthcare system.

As the largest health IT company in the world, McKesson is focused on the transformation of health care from a system burdened by paper to one empowered by interoperable electronic solutions.

There is a significant opportunity to improve our healthcare system, but to do so, we must fundamentally transform how care is delivered. We need to move from a fragmented model of care, where each patient visit is disconnected, to a model where care is coordinated across the entire continuum. Interoperable health IT is foundational to this transformation.

I would like to share today two recommendations which will advance health care in the 21st century. First, we must align payment and coordinated care models in order to create an environment that fosters interoperability; and second, we need a new risk-based regulatory framework that is specific to health IT.

We don't today have an easy, uniform way to move patient data between care settings. The interoperability we need requires collaboration among all stakeholders to develop uniform standards, coordinated policies, and the necessary infrastructure to promote interoperability and assure coordination of care.

ONC has provided an important role in providing common guardrails for the exchange of health information. It is important that we maintain flexibility within those guardrails to allow for industry innovation. One example of innovation and interoperability is the CommonWell Health Alliance. CommonWell was founded by McKesson in partnership with our competitors to develop a software solution that will share patients' data, with their consent, across multiple settings of care. We have made significant progress in endeavor over the last 18 months. It is essential that we are able to share the right patient data in the right place and the right

time. This solution is imperative to creating a new model of coordinating care.

Fostering innovation in the private sector is critical, but there is also a role for Congress to play. Policy changes are needed to reflect current advances in technology and promote ongoing innovation. A 21st century health system demands 21st century policies. We support a new regulatory framework that would establish three categories of health IT. Oversight of each category would vary according to potential risk to patients and the role of the clinician.

The FDA should continue its important role in regulating software with the highest potential risk; however, we believe Congress should amend the Food, Drug and Cosmetic Act to define each of these categories of health IT and provide clarity that clinical and administrative software should not be regulated as medical devices.

To realize a true 21st century healthcare system, we need fundamental change in our healthcare delivery model. We need to replace our fragmented system with patient-centric coordinated care. This transformation has begun, but we need to accelerate the pace of change, and to do this, we must harness the power of technology. Specifically, we must align reimbursement and payment models to promote the adoption and also the interoperability of health IT, and Congress must update the law to codify how health IT is regulated in a way that, while assuring patient safety, is predictable and fosters innovation. The result will be better outcomes, better access, better cost efficiency, and better experiences for patients and their families.

Thank you for the opportunity to testify today.

[The prepared statement of Mr. Niloff follows:]

STATEMENT OF

JONATHAN M. NILOFF, MD
VICE PRESIDENT AND CHIEF MEDICAL OFFICER
MCKESSON CONNNECTED CARE & ANALYTICS

BEFORE THE
SUBCOMMITTEE ON HEALTH
SUBCOMMITTEE ON COMMUNICATIONS AND TECHNOLOGY
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

21ST CENTURY TECHNOLOGY FOR 21ST CENTURY CURES

JULY 17, 2014

Good morning Chairmen Walden and Pitts, Ranking members Pallone and Eshoo and distinguished members of the Subcommittees. My name is Jonathan Niloff, and I currently serve as Vice President and Chief Medical Officer for McKesson Connected Care & Analytics. I appreciate the opportunity to appear before you today.

My background includes practicing as a gynecologic oncologist, serving on the faculty of Harvard Medical School and as president of a hospital physician network in Massachusetts that was accountable for the quality and cost of care for over 450,000 patients. I was also the founder and Chief Medical Officer of MedVentive, a provider of population and risk management tools developed to improve healthcare quality and cost for health systems, multispecialty clinics and payers nationwide. In my current role at McKesson, I consult with hospitals and health systems across the country and engage in the development and deployment of health information technology solutions that improve the quality of patient care. These experiences have reinforced my belief in the imperative for innovation in health information technology (health IT). I have

seen first-hand the power of health IT to improve outcomes, reduce costs and, perhaps most importantly, accelerate the pace of change in our healthcare system.

For over 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. As the nation's largest distributor of pharmaceuticals, we pride ourselves on the efficiencies that we bring to the healthcare system every day by delivering one-third of all medicines safely and rapidly to pharmacies, hospitals, physician offices, skilled nursing facilities and government locations, including every Department of Veterans' Affairs facility, across the country.

As the largest health IT company in the world, McKesson has decades of experience serving the health IT needs of the largest and most diverse provider base in the industry, including 52 percent of our nation's hospitals, 20 percent of all physician practices and 16 percent of home care agencies, which support more than 50,000 home care visits annually. We process billions of financial healthcare transactions among physicians, hospitals, pharmacies, insurers and financial institutions, and provide care and claims management solutions to most of America's health insurance companies. Through RelayHealth, McKesson's connectivity business, McKesson is connected to more than 90 percent of U.S. pharmacies. We serve as the Centers for Medicare & Medicaid Services (CMS) Transaction Facilitator for the Medicare Part D prescription drug benefit. We manage millions of aggregated personal health records as the leader in connecting patients online with their physicians, hospitals, reference laboratories and health plans and as a participant in community and regional health information exchanges. Our connectivity business enables population and performance management analytics that support new payment and delivery models.

In short, we are actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and advance healthcare efficiency.

There is a significant opportunity to improve healthcare in this country. While we continue to achieve better care for specific diseases through new drugs and new devices, we have an

opportunity for greater impact if we can fundamentally transform our care delivery system. We need to move from a fragmented transactional model of care where each patient-clinician encounter is disconnected from the other to a model where care is coordinated across the continuum and where, while optimizing the care of every individual, we are managing populations proactively.

Interoperable health IT is foundational to this transformation. We cannot change the healthcare delivery model without it. Health IT will drive quality improvements, make our care delivery system more efficient and improve the experience for patients and their families. The automation provided by technology will allow us to cost effectively achieve these goals at scale.

Today, I want to share two recommendations, related to technology, which will significantly advance healthcare in the 21st century:

First, we must align payment and care models to fully harness the potential of interoperable technology. Coordinated care can dramatically improve the quality, safety and affordability of healthcare, but this new care model must be built on a foundation of interoperable health IT.

Second, we need a new risk-based regulatory framework that is specific to health IT. A new framework will foster innovation in the development of health IT solutions and leverage the power of those solutions to transform healthcare.

New Care Models for the 21st Century

To transform our care delivery model, we must first solve the challenge of interoperability. Today, our healthcare delivery system lacks a universally adopted, easy, affordable way to allow the frictionless movement of patient-centered data across all settings of care.

Achieving widespread interoperability requires a multifaceted approach. Over the last few years, industry has made significant progress. Vendors are collaborating and improving their products to offer a more interoperable solution to their customers, and we need to continue to support and encourage this progress. As provider organizations evolve their models to focus on value rather

than volume, we must align reimbursement and payment systems to promote coordinated care powered by seamless interoperable connectivity. The Office of the National Coordinator for Health IT (ONC) should continue to provide common guardrails for exchange of healthcare information while providing flexibility within those guardrails to allow for industry innovation.

McKesson supports a collaborative effort among all healthcare stakeholders to develop uniform standards, coordinated policies and the infrastructure necessary to support secure health information exchange to promote interoperability among IT systems. This collaboration will allow for the development of longitudinal patient records across all settings of care and will support the coordination of care between post-acute, long-term, and inpatient settings to proactively prevent readmissions and effectively manage care transitions.

Interoperability is becoming a reality. Automation is here, and efforts to align payment models with care models supported by the exchange of health information will spur the market to innovate and, ultimately, transform our healthcare system for the 21st century.

Interoperability and CommonWell™ Health Alliance

An example of innovation and interoperability in the private sector today is the CommonWell Health Alliance. CommonWell is an independent association, founded by McKesson in partnership with our industry competitors, to create vendor-neutral services and standards that will break down the barriers currently inhibiting effective health data exchange. Today, its members include McKesson, RelayHealth, athenahealth, Cerner, Greenway, Allscripts, CPSI, Sunquest, Brightree, MacPractice, MEDHOST and CVS Caremark. The goal is to dramatically improve the quality and cost effectiveness of care nationwide by enabling seamless sharing of patient data, no matter the setting of care, with the individual's consent.

Currently, services provided by CommonWell facilitate patient consent, identify and match patient records across healthcare settings, securely access clinical data in near real-time regardless of where the care was delivered, and transfer the data directly to existing health IT software systems.

We have made significant progress in 18 months. In the near future, patients will be empowered to manage their healthcare and better able to utilize new electronic tools to manage and authorize those who can access their medical history. Technology barriers will no longer constrain who can access a person's record; with appropriate consent, technology will instead support a trusted network for accessing and managing the delivery of the right data, to the right place, at the right time.

Interoperability and Coordinated Care

A good example of the power of interoperability and coordinated care may be found in the military health system. Since 2009, RelayHealth, a division of McKesson, has provided a patient engagement portal solution to the Defense Health Agency, which includes the joint services of Navy Medicine, Air Force Medical Service, the Army Medical Department and the National Capitol Region Medical Directorate.

Today, this system manages over one million patient connections to over 25,000 clinical users, including physicians, nurses, pharmacists, medics and corpsmen at every military treatment facility, branch clinic and community-based medical home around the world.

Servicemen and women, retirees, and their families can access this patient portal online to connect to their healthcare teams and records, both inside the military healthcare system as well as with a growing network of civilian healthcare partners. This portal enables them to manage medical appointments, arrange webVisits®, communicate with medical providers and staff, receive alerts for important check-ups or vaccines, request medication refills, and access educational materials on medical conditions or prescriptions. More than 35,000 new members of the U.S. Armed Forces and their families enroll in this patient portal each month throughout the world. The service has a 94 percent patient satisfaction rating.

This portal is helping the Military Health System create a stronger patient-centered and coordinated care model to meet their goals of improving the care experience, reducing the per capita cost of care and improving safety and outcomes while ensuring the readiness of the force.

We have the potential to replicate the success of this patient-centered coordinated care model among widespread populations, but we cannot get there without making these innovative solutions interoperable. Patients and their providers must be able to seamlessly access information about the care they receive across multiple care settings.

Health IT Innovation for the 21st Century

Fostering innovation in the private sector is critical to healthcare transformation, but there is also a role for Congress to play. Policy changes are needed to reflect current advances in technology and promote ongoing innovation. A 21st century healthcare system demands 21st century policies.

McKesson has endorsed a new regulatory framework for health IT recommended in the Bipartisan Policy Center 2013 report: *An Oversight Framework for Assuring Patient Safety in Health Information Technology*. The new framework establishes three categories of health IT according to potential risk to the patient and the opportunity for clinical intervention. We believe Congress should amend the Food, Drug and Cosmetic Act to establish guidelines defining each of these categories of health IT and then oversee implementation of these guidelines by federal agencies. Specifically, the Act should be updated to provide clarity that clinical and administrative software should not be regulated as a medical device.

Conclusion

To realize a true 21st century healthcare system, we need a fundamental change in our healthcare delivery model. We need to replace a fragmented transactional system with patient-centric coordinated care. This transformation has begun, but we must dramatically accelerate the pace of change.

To do so, we must harness the power of technology. We must align reimbursement and payment models to promote not only the adoption, but also the interoperability of health IT. Congress must also update the law to codify how health IT will be regulated in a way that is predictable and fosters innovation while assuring patient safety. If we are successful, the result will be better outcomes, better access, better cost efficiency and better experiences for patients and their families.

McKesson appreciates the opportunity to share our views on 21st century cures in health IT with the members of the Subcommittees. We look forward to continuing to work with you toward transforming our healthcare system through the development and use of technology.

SUMMARY STATEMENT

JONATHAN M. NILOFF, MD
VICE PRESIDENT AND CHIEF MEDICAL OFFICER
MCKESSON CONNNECTED CARE & ANALYTICS

21ST CENTURY TECHNOLOGY FOR 21ST CENTURY CURES

JULY 17, 2014

My name is Jonathan Niloff, and I currently serve as Vice President and Chief Medical Officer for McKesson Connected Care & Analytics. As the largest health IT company in the world, we are actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions.

My background includes practicing as a gynecologic oncologist, serving on the faculty of Harvard Medical School and as president of a hospital physician network in Massachusetts. I was also the founder and Chief Medical Officer of MedVentive, a provider of population and risk management tools developed to improve healthcare quality and cost. I have seen first-hand the power of health IT to improve outcomes, reduce costs and, perhaps most importantly, accelerate the pace of change in our healthcare system.

To realize a true 21st century healthcare system, we need a fundamental change in our healthcare delivery model. We need to replace a fragmented transactional system with patient-centric coordinated care. This transformation has begun, but we must dramatically accelerate the pace of change.

To do so, we must harness the power of technology. We must align reimbursement and payment models to promote not only the adoption, but also the interoperability of health IT. Congress must also update the law to codify how health IT will be regulated in a way that is predictable and fosters innovation while assuring patient safety. If we are successful, the result will be better outcomes, better access, better cost efficiency and better experiences for patients and their families.

Mr. WALDEN. Dr. Niloff, thank you for your testimony. Thanks to all our witnesses.

We will go vote and then members will come back and ask questions. We are probably going to be gone at least a half an hour, I would assume, so if you need to take a break, it is a good time. We will reconvene immediately after votes. Thank you very much.

We stand in recess.

[Recess.]

Mr. WALDEN. I will call the subcommittee back to order and appreciate again the testimony of our extraordinarily distinguished panel of witnesses. Thank you very much.

And don't think you are off the hook because I think what you have given us here is very important, and we will be following up, I am sure, over the months and years ahead to dive deeper with you on how we can all get this right.

I am going to start off with questions, and the first one goes to Mr. Misener. Are there any laws or regulations that have impacted the development of the cloud that we should take a look at deeply, change that hinder what we are trying to accomplish here, what you are trying to accomplish here?

And obviously we have got to protect data and privacy and security and all that, but are there other things we should be aware of that would facilitate advancements in the sectors we are talking about today?

Mr. MISENER. First of all, thank you for the question, Mr. Chairman. There are areas in which Government could lead, provide an example to private industry, and one particular roadblock we have run up against over the years trying to serve Government institutions including the U.S. Federal Government and its agencies, is that there is oftentimes money set aside for agencies to buy computers, to buy software, to invest capital essentially which is highly inefficient when instead money could be allocated for purchasing service, making it an operational cost rather than a capital investment.

And the Government could not only be able to be much more flexible that way, in other words, only purchase what is needed and then discard it if it is not needed, but also it allows Government to scale up and scale down as necessary. But we have also often run into problems where agencies are only given authority to buy specific things like hardware or software when actually they should be able to have the freedom to obtain services instead.

Mr. WALDEN. Got it. So on another issue, and back to you, Mr. Misener, and if others want to weigh in on these subjects, please feel free to do so. But, how can we modernize HIPAA to ensure that patient information is protected but that we can still utilize data? There are other countries that have laws that protect patients but also facilitate data sharing and leveraging the research being done.

I know in our round table that Chairman Upton convened recently, Dr. Brian Druker who heads the Knight Cancer Research Center in Oregon, talked about I think it is 65 petabytes—did I say that right?—of data, just involving cancer patients that could be harnessed to do an analytic work and all and research. Are there

some issues with HIPAA; are there things we should be looking at in that respect?

Mr. MISENER. There are, Mr. Chairman. It is not a huge barrier at this point, but what we would like to be able do is recognize that there are sometimes when information is stored in the cloud where it is known to be health information and it is accessible to the cloud service provider. But most of the time that is not the case. We don't know what information is stored there, and it is also encrypted, so we can't get at it; and yet we still have to go through HIPAA hoops as if we had access to the information.

Mr. WALDEN. So what would that mean in real laymen's terms?

Mr. MISENER. It means the health care enterprise that is storing data on our servers, has HIPAA requirements placed upon it, but those requirements are also placed on a cloud services provider, even though it is entirely unnecessary. We can't see that data, and usually we don't even know it is there.

Mr. WALDEN. But from a practical standpoint, what does that mean in your company you have to do?

Mr. MISENER. I think it means asking NIH not to interpret the rules so broadly as to require a cloud services provider to comply with HIPAA where it is not necessary. But of course we do comply with HIPAA, Amazon Web Services does, when it is necessary.

Mr. WALDEN. OK.

Dr. Niloff, what are the technical challenges your company is facing as you work to innovate in health care that we might need to take a look at, besides what you outlined in your testimony?

Mr. NILOFF. Sure. So, I think the major technical challenges involve interoperability, and the typical environment in the health care system is very heterogeneous with multiple different EMRs and multiple different other systems that we need to connect to.

Mr. WALDEN. EMRs being electronic medical records?

Mr. NILOFF. That is correct, sir. And solving that challenge, the technical challenge of connecting such heterogeneous environments, is a big barrier today.

Mr. WALDEN. All right, anybody else want to weigh in on these topics.

Mr. VOCKELL. I would say the HIPAA question initially, the inability of patients to give up their right to privacy, like the HIPAA requirements are kind of universal whether it is I have a cold or whether I have HIV. And there are some conditions where let's say I had celiac disease, I would love to tell everyone on earth that I have it because most likely that is how I am going to find out better ways to take care of myself. But because of HIPAA, I can't even email my doctor.

And so I think if there were additionalopportunities, let's make it super simple. I want to email my doctor; he wants to email me back, but we don't because it is against HIPAA for him to send me health information, but both of us would agree that it is OK for me to talk about my kid's fever through email. So I think what that kind of example we have around regulation is that when the FDA kind of took their very vague some mobile stuff might be good, some mobile stuff might not be good and made it we are all hanging around.

And they said, all right, you guys can leave the room; you guys come in, we want to talk some more, and you guys stay close, that changing very gray to more black and white allowed a lot of people to innovate and build something and do stuff.

Mr. WALDEN. Yes. We did an oversight hearing on that very issue about a year ago because nobody was getting clarity whether your iPad was a medical device or not, and we got them to admit some of those things.

Mr. VOCKELL. I would have stood up and applauded. But I think similarly with HIPAA, if there could be another layer of, this is what is covered, and this is what isn't; it is OK to email your doctor about your kid's flu, that would do a lot to create innovation points for better care.

Mr. WALDEN. All right. Thank you.

I have overextended my time. I will now turn to the gentleman from New Jersey, the ranking member on the Health Subcommittee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you.

Reading the testimony today, I was impressed by how much progress we are making towards a more technologically advanced health care system, and one important step the Federal Government is taking to encourage this innovation is to open up much of the data it collects to the public. That allows developers, programmers, and academics to dig into this data and develop new tools to help improve our system.

I wanted to ask Mr. Vockell, can you talk more about how you have put this open data to use and the potential benefits of this increased transparency over the long-term?

Mr. VOCKELL. Yes, thank you very much. Lyfechannel—about six months ago, CMS released the big data set around exactly what every provider for Medicare charges for every protocol. And a couple weeks ago at the Health Datapalooza, which is a lovely name that I think Todd Park came up with, that Government and public agencies come together to talk about the incredibly exciting topic of health data. They had a competition to say for this big data set, who can make it into something super interesting.

And Lyfechannel 1, largely based on some research that we did at the International House of Pancakes, the good example that CMS sets is they release data before it is totally perfect. The CMS data was 50 percent actionable. But we said early and they give entrepreneurs or any great data analytics house a chance to churn through it and pull out what they can and then make recommendations on what the next version of the data should look like.

I think the more that holders of that health data are encouraged to kind of release it when it is excellent, not when it is perfect, will allow entrepreneurs to get up on it like a shark and reveal if there is something inside or help identify what the next round of it should look like.

Mr. PALLONE. Thank you. I think the steps that CMS and the other Federal agencies have taken in this area are really important. I wanted to ask Dr. Riskin, in your testimony you state that health quality measures are often selected because they are easy to track. Could you elaborate on your recommendation that we

need more accurate and meaningful quality measures in health care?

Mr. RISKIN. Yes. Thank you for your question, Mr. Pallone.

The challenge is whether we try to develop measures for what is easy to do today or whether we create a target for what we need to do to improve health care. If we create a target for what we need to do to improve health care, we won't be able to hit it today. The technology doesn't exist. If we don't, if we pick what is easy, then we won't actually meaningfully reduce costs in health care in a short term.

So to give an example, an easy quality measure would be, are you counseling people for smoking cessation, and a hospital might meet that measure by on every discharge summary writing, you should not smoke. That doesn't do a lot of good if it is buried five pages down and mostly put in for non-smokers anyway.

On the other hand if the measure is, do you smoke and that ties to an outcome like reduced costs and improved quality of care, that is the kind of measure that is meaningful. We don't do a lot of that because it is so hard to measure, but over time the really robust analytics companies will figure out a way to hit that target if the Government makes that known that that is the target to hit.

Mr. PALLONE. Thanks. And, Mr. Jarrin, in September last year, FDA issued a final guidance on mobile medical applications. It provides a long list of applications that FDA does not intend to regulate at all. Basically I just wanted to get your views on this guidance. I mean, do you think that the FDA struck a proper balance between protecting patients safety on the one hand and allowing innovation to flourish on the other? And do you see any risks in trying to legislate in this area?

Mr. JARRIN. I think FDA did a good job by issuing the final guidance on mobile medical applications. It was definitely very different from the original draft. The original draft basically just restated the law without any clarity and without any vivid example.

In the final draft guidance, they provided numerous examples of what they were putting under enforcement discretion, enforcement discretion being the ability for the agency to state publicly we are not going to obligate regulatory requirements on certain medical devices. Even though by definition they are medical devices, we are not going to require regulatory obligations. So I think that was very helpful to the industry.

Mr. PALLONE. What about the risk though in trying to legislate in this area?

Mr. JARRIN. I am not sure I would say that there is a risk in legislating the area. I think that that was the next evolution to what Congress had originally intended through FDAISA. Through FDAISA they had asked for a risk-based regulatory framework. The agencies then came out with that through the FDAISA draft report that they are contemplating currently. I think it is now the next step for Congress to decide whether it would like to go in and make those recommendations, you know, codify them. That is a higher pay grade than me.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. [presiding]. The Chair thanks the gentleman.

I will recognize myself 5 minutes for questions.

Mr. Misener, in your testimony you suggest that Congress work with NIH to establish and support the cloud-based management platforms. Can you expound a little bit more on why you think this is so important? What are some of the benefits cloud-based platforms might lend to 21st century cures?

Mr. MISENER. Thank you, Chairman Pitts.

Modern biomedical research is a highly collaborative process. All scientific research these days is collaborative. The days of a major breakthrough coming from a sole, an individual working with a Bunsen burner and a test tube, it is over. You only need to look at some of the scientific journals and see the lists of authors. It is no longer unusual to see hundreds of authors listed in a major scientific paper, even over a thousand.

And so that kind of co-research requires collaboration. And if the Federal Government can establish a way for federally funded researchers to share their information, even outside their normal channels of collaboration, it will become far more efficient and more productive.

Mr. PITTS. And you mentioned one other concrete step that you recommended as we decide, if we decide to support this endeavor. List some other concrete steps that Congress can take. One was clarifying HIPAA. What are others?

Mr. MISENER. Well, there are two bills that the House has already addressed—and hopefully they will be addressed in the Senate, as well—that actually would assess the Government's provision or accommodation of cloud computing for scientific agencies, and another would clarify Government agency's ability to obtain cloud services in lieu of hardware and software. Both of those are important pieces of legislation, not only on their own merits or on their own rights of what is going on within the U.S. Federal Government, but as setting an example to State and local Governments, to private industry, to Governments in other countries, that there is a great deal of efficiency that can be gleaned from the cloud in dealing with collaboration that I mentioned and also just the massive amounts of data that now go into any form of scientific research, including biomedical research.

So Government setting an example, I think, is something that Congress can be part of right now.

Mr. PITTS. You mentioned Amazon worked with FDA to turn 900,000 handwritten reports of adverse drug effects each year into machine-readable information with 99.7 percent accuracy, reducing the cost from $29 per page to 25 cents per page. This Cures Initiative is in part focused on using technology to relieve administrative burdens for agencies such as FDA, so they can use the resources to invest in more researchers and new development methods such as biomarkers. Do you have other suggestions for other ways we can increase efficiency at FDA or other agencies?

Mr. MISENER. Yes, Mr. Chairman. There is a model of scientists doing things that they don't need to be doing.

One would be for example, I don't know, producing their own electricity for their laboratories. You don't want them out in the back of the laboratory working on a diesel generator just so their labs have lights. Likewise, you don't want them to have to be tin-

kering with computing equipment, either for storage or for computation, in a way that that could easily be provided like a utility, like electricity. So let's figure out ways to allow our scientists to be scientists, our doctors to be doctors, and not have to have them be information technologists at the same time, even though as part of the collaboration and the data-intensive work that they are doing, computation is absolutely necessary. It is just that they don't need to be the ones doing it.

Mr. PITTS. Now, we talked a little bit about HIPAA. Are there other countries that have laws that protect patients but also facilitate data sharing, leveraging the research being done? Any of you who would like to——

Mr. VOCKELL. Yes, I am not familiar with other countries' details.

Mr. PITTS. Anyone familiar with other models?

All right, let me just go finally—one common recommendation was for fully harnessing the potential of interoperable technology. Are we talking about just electronic health records, or do you think that medical devices, other health care sources of data should be interoperable, if you will elaborate on that any of you?

Dr. Niloff?

Mr. NILOFF. Yes. Thank you. I think that the interoperability has to extend beyond just electronic health records. There are multiple sources of both clinical and non-clinical data that are important to aggregate together with the clinical data in electronic health records, and that interoperability should exist.

There are also a variety of an analytic solutions which are important to improving population health. So solutions that identify patients that are likely to be hospitalized, patients who have progressing illnesses, and the ability to link clinical and claims data with those type of systems to allow the early proactive intervention in the care of those patients, is a very valuable intervention to driving improved health, decreasing hospitalizations, and decreasing emergency room visits.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentlelady from California, Ms. Eshoo, 5 minutes for questions.

Ms. ESHOO. Thank you, Mr. Chairman.

I want to say to each of you, "Bravo." I think every single one of you have been terrific witnesses, and you have given us—which is so important in a hearing, instead of starting with Adam and Eve, you have gone right into the meat of the subject matter to make recommendations for us, and that really is so helpful. So thank you to you.

On this issue of interoperability, obviously there is more than one part of it, and what I wanted to ask you, Dr. Niloff is, is there anything that the Government is doing today that stands in the way of interoperability, as you just described it; i.e., in patient's record, is a physician prohibited from putting in the last line these are the most important things to track with this patient? I am not a doctor, so I am probably not stating it, you know, as beautifully as I should.

But I am trying to figure out where we have regulations that need to be written, where we have regulations that don't make any

sense anymore, or what we need to write and put on the books, and all of these areas are really important. So can you answer my question?

Mr. NILOFF. Sure. Thank you. So, electronic medical records typically have a lot of flexibility but we are——

Ms. ESHOO. Thank you. I helped write the legislation on it, so it is nice to hear.

Mr. NILOFF. But, you know, I think that with electronic health records and the rest of healthcare technology, we are at the beginning of a journey, and it is a journey that is going to take us many years to get to both to the level of sophistication in the solutions and in the level——

Ms. ESHOO. But specifically, though, when it comes to interoperability and electronic health records, are there regulations that you think don't make sense, or are you calling for something that will help advance interoperability? We deal with interoperability all the time at communications and technology relative to the telecommunications industry. This is a different deal. That is why I am probing here.

Mr. NILOFF. Sure. I think that the thing that will drive interoperability the most and where the Government can have the greatest influence, is in making the business case for interoperability for those who are going to pay for it and what that means is that we need to align the payment models.

Ms. ESHOO. I think that for the most part now is private sector though, because there were initial grants or whatever to get the electronic records going. I think that money has been spent. So I don't think we are players in it.

Mr. NILOFF. If I may, I am not talking about direct incentives. What I am referring to is that——

Ms. ESHOO. We need to speed it up. I have 1 minute and 20 seconds left. You have had 4 of my minutes almost.

Mr. NILOFF. OK. I apologize.

Ms. ESHOO. That is all right. Go ahead.

Mr. NILOFF. How we pay for medicine and what I mean by that is if we are doing global payments, if we incent the delivery model to do a coordinated care model and the payment is aligned with the delivery model——

Ms. ESHOO. I understand that part of it.

Mr. NILOFF. We will drive the adoption of this type of technology.

Ms. ESHOO. Well, thank you very much.

To Dr. Riskin, I see you nodding, and I think you want to say something.

Mr. RISKIN. So to the same question, there are choices that are being made right now that could be better. So the choice for interoperability right now is we only share information out of the electronic health record that is perfectly structured, meaning only information——

Ms. ESHOO. So how do we make this more robust and meaningful so that the right information is extracted because that feeds through the whole system?

Mr. RISKIN. Sure. So if a doctor wrote right now what is really important here is these three things, that would be ignored and never shared. What is needed is——

Ms. ESHOO. But the Federal Government shouldn't be instructing doctors how to write something.

Mr. RISKIN. It doesn't matter how—the doctors will write what they write, but the Federal Government is instructing what needs to be shared in interoperability format.

Ms. ESHOO. So share is the operative word?

Mr. RISKIN. That is right. And if we share all of the information, then the analytics companies can pick up the useful information.

Ms. ESHOO. I just have so many questions, but my time has run out. I think what I will do is to submit questions to you both about the cloud, software, hardware; that is another whole thing. I am so thrilled that your mother, that you told a beautiful story, and it means a lot, I think, to all of us. Certainly to you.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentlelady.

Now recognize the gentleman from Illinois, Mr. Shimkus, for 5 minutes of questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. It is great to have you all here, and I am going to try to be quick, too.

But I am going to just segue right after my colleague Congresswoman Eshoo's question, is getting out of order the way I wanted to go.

But, Mr. Riskin, this data information is really the crux, and so I am concerned that, or the question is, if you are going into the genomics debate and personalized medicine, the data, are we in the way because of HIPAA or some other rules and regs that we are afraid to put the data available to a larger field because of the rules and regs we have in place?

Mr. RISKIN. Yes. Thank you for the question. Yes, certainly the privacy and security policies make it tougher to share data. With that said, I am one of the biggest proponents of keeping data safe. We are asked as a big data company to use genomic data and combine that with phenotypic data, the clinical information, and figure out what it means. Keeping it safe is critically important. That doesn't mean that you shouldn't share it safely. So if the private sector can keep it safe and follow regulations to do that but there is also a requirement that the information come out in certain formats so it can actually be used, that is a very powerful setup, so all of the data we have paid to collect can be used to do meaningful things.

Mr. SHIMKUS. So let me move to Mr. Misener on kind of the same talk. A lot of folks are afraid to go into this field because they have done a business analysis. They don't know if there is a return on investment. You guys have decided to try and move in this, and so data storage and computation is the area that you think obviously can get you a business model plus improve.

You know, I am a market capitalist, so we don't get these investments unless there is a return on investment. We don't get that unless there is improved health access and the like. So is that the model, the business model that you think that you all can do is this big data storage and computation while keeping that data safe and secure.

Mr. MISENER. Yes, Mr. Shimkus. We very much believe in this business. We are very passionate about it as well. We kind of

backed into it as a retail company online. We figured out at one point that, gee, we have a business in keeping data safe and organizing it and storing it and being very efficient about it. So we started making it just kind of a service available to developer customers. We think in the medical field, the medical sector, there are many opportunities for the storage and sharing of data in a way that is highly secure.

We not only believe that security is incredibly important to our business, but it is actually much easier to do at scale. We have the ability to provide security measures in the cloud that just aren't available for local storage of information and so we are passionate about it, and I think we are an enabler of the genius that you see at the table here.

Mr. SHIMKUS. Just because I want to get the last two in. In the mid 1970's, Congress defined medical devices, which I think for the most part people thought at that time was good and helpful. The question is, is it time for us to look at codifying terminologies to help us through these processes? I mean a lot of us talk about FDA and how do we expedite, but don't you think it might be time to look at some new words and definitions and define them in the law so that we can get some application speedily and I just kind of throw that up as a comment. Anyone want to jump in real quick? I got one more question so if you can be brief.

Dr. Niloff?

Mr. NILOFF. Yes, so I believe that, that is very important. You know, when I went to medical school, we didn't have computers. This is all new stuff, and that is the era the law was developed, and I think that we need sort of new law that conforms with the state of the world as it exists today. I think that is really essential to driving investment.

Mr. SHIMKUS. Let me follow up because your testimony, you really talk about developing a new risk-based regulatory framework that is specific to health information technology. With my remaining time do you want to talk about that a little bit?

Mr. NILOFF. Sure. So you know, I think it is essential. I go back to you know, when I started my company. I raised four rounds of venture capital, and the process was very similar every time. Once you figured out the business model with the investors, they wanted to know two things. What's the IP issues or the patent problems, and what is the regulatory environment and how is that going to affect their investment and the risk of their investment, and it happened every time.

And also predictability, a stable environment where everything is codified and predictable is critical, and it has to be over the long-term. I thought one round was going to do it, and I was all set, but we ended up with four rounds. And it is a long process, you need a stable environment for it to drive technology and innovation.

Mr. SHIMKUS. Thank you.

Mr. PITTS. The Chair thanks the gentleman.

Now recognize the gentleman from Texas, Mr. Green. Five minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman. Again, thank you for calling the hearing on joint telecomm and health care.

In a July 4th article in Forbes the co-founders of Google were asked if they would imagine Google becoming a health company. Their response was no. To quote Mr. Page, "generally health is so heavily regulated, it is a painful business to be in. Even though we do have some health projects, we will be doing that in a certain extent, but I think the regulatory burden of the U.S. is so high I think it would dissuade a lot of entrepreneurs. In my experience this is not an isolated sentiment from the tech community."

Doctor, now in your experience, is Google's view of innovation in the health care sector a common one?

Mr. NILOFF. Yes, sir. You know, I think as I have had you know, sort of lots of opportunities over the years when I was running my company to meet with other entrepreneurs and largely through forums through our investors, and this was a common topic of discussion. You know, overregulation is an inhibition to investment and an inhibition to innovation.

So having, as I just stated, a stable environment that is predictable and where we are not prohibiting investment and therefore innovation is important and I believe widespread.

Mr. GREEN. Well, just from what some of us know, and this is such a good coordination of these two subcommittees because of what we can do with the combination of the high tech and the health care, it literally could open up so many avenues for folks. I know there are some supporters of the current regulatory approach of health care that suggest that the regulatory uncertainty under the FDA is a proper approach, which I don't obviously agree with that.

However, my constituents are concerned when leaders in the tech space like Google suggest health sector is an unwelcome place for innovators. Frankly if that is true, millions of patients will be harmed, and this is a huge problem.

Dr. Niloff, what can we do to attract more tech innovators into the health care space, and can Congress play a role in helping to create more certainty for innovators in the health care space?

Mr. NILOFF. Yes, thank you. So, I think that there are two things. I think that the first thing reflects on my previous comment, is we need an environment that from a regulatory point of view that drives investment, and that is all around certainty about the future so that that doesn't become a barrier, we don't have, if you will, a risk premium on investments related to health IT.

I think the second area is certainty or greater certainty about what the environment is going to be, the delivery environment is going to be, and how we are going to pay for health care in that environment, so that there is greater certainty around what the market is going to be for these innovations.

And specifically I am referring to, from a congressional perspective, is that CMS with respect to the various programs that it promulgates defines the payment model, and the private sector commonly follows what is promulgated by CMS. Providers are challenged when they have to work in part fee for service world and part accountable care world, and you need to reach a tipping point where enough of your business is in the accountable care world, and I called it the coordinated care world, so it is worth making the investments in the technology to support that care model.

To the extent that collaboratively between the private sector and the public sector we can drive past a tipping point, where investments in technology make sense and are economically sound, we will both help our healthcare delivery systems be more viable and successful while at the same time driving better access, better quality, better patient safety, and more cost effective care.

Mr. GREEN. Thank you.

My colleagues, we have legislation called the Software Act to establish a commonsense approach to regulating mobile apps and other health information technologies under the FDA and our work is a work in progress, and our office has worked with Ms. Blackburn, Mr. Butterfield, Chairman Walden and others that takes into account the feedback we have received from various stakeholders over the last few months.

And I would commend my colleagues on their leadership but also the important issue we could urge the chairman to address this in the 21st Century Cures, and that is what you just said is something I keep hearing. We need to have a payment system that reflects, are we going to go to the outcomes-based, or are we just going to continuing with the same pay for procedure, and maybe we need to provide leadership from that.

Mr. Chairman, thank you for having this hearing.

Mr. PITTS. The Chair thanks the gentleman.

Now recognizes the gentleman from Georgia, Dr. Gingrey, 5 minutes for questions.

Mr. GINGREY. Mr. Chairman, thank you, Chairmen Walden and Pitts, and thank you for holding today's joint hearing on an important nexus within the jurisdiction of the full committee.

I would like to focus my line of questioning on a topic that has been the focus of the committee for a long time. Ms. Eshoo was getting to that point as well. Innovation and health information technology, HIT. Dr. Niloff, you state in your testimony, and I quote, interoperable health IT is foundational to health care transformation. We cannot change the health care delivery model without it. Do you believe that we are on the path to interoperability, or are there changes to the law that we should consider as part of the 21st Century Cures Initiative?

Mr. NILOFF. Thank you, sir. I believe that we are on the path. I think it is a challenging and long journey. I think we can help accelerate that path with some of the suggestions I made in the response to my last question.

I think a good example of that is the work that we have accomplished with the Commonwealth Alliance where we have brought together essentially competitors to collaborate and work together to be able to move patients' health information with their consent around a health care system. We have pilots in place today. It is working. We have tremendously positive feedback from both patients and providers, so I think, sir, that we are, indeed, on the path.

Mr. GINGREY. Well, I agree with what you said, and I hope we are, but I am very concerned, the Rand Corporation report that was published last month found that the main electronic health record vendor, with over half of the stimulus dollars paid out to

medical providers going to their customers, was operating a closed platform which in essence means that they cannot be interoperable.

And Congress has spent, as we all know, something like $24 billion over the past 6 years buying products to facilitate interoperability only to have the main vendor under the program, Epic, sell closed platforms. Do you believe that the Federal Government and the taxpayers are getting their money's worth subsidizing products that are supposed to be interoperable but they are not? And I will ask any of the panel if they want to weigh in on that. Yes, Mr. Jarrin.

Mr. JARRIN. If I may Congressman, thank you.

One of the aspects that we have been pushing for when we discuss interoperability is medical device interoperability, and I mean very specifically home use medical devices because interoperability can be many things. Health information data exchange between electronic health records, that is one aspect, systems-wide within a hospital, and that would include high acute medical devices. That is another kind of interoperability.

But when you leave a care facility, the electric health records incentive payment program right now that is run by CMS and the ONC which you have quoted, the $24 billion, I believe it goes all the way up to $27 billion, not really much of that really engages patients and families in their care.

As part of the meaningful use stages, stage one, stage two, and stage three, in stage one they described that they were looking at potentially including uploading patient-generated health data into the electronic health record. That would be a way of interoperability. That happens right now because there are many companies that are actually doing that and allowing medical device that is are used at home, like wireless glucometers for example, wireless sensors on inhalers, et cetera. That information can go straight into a portal. It can easily go into an electronic health record, but that is not something that is happening at all and part of that is because the meaningful use stages have not actually stated that very directly. They should.

Mr. GINGREY. Well Mr. Chairman, this committee has primary jurisdiction over the Office of the National Coordinator, ONC, and the HITECH Act that is responsible for the tens of billions of dollars being spent on non-interoperable products, if the June 2014 Rand report is true, we have been subsidizing systems that block information instead of allowing for information transfers, which was never the intent of the statute. It may be time that this committee take a closer look at the practices of vendor companies in this space, given the possibility that fraud may be perpetrated on the American taxpayer.

Furthermore, Mr. Chairman, as I see my time is elapsed, I would like to ask unanimous consent to include in the record an article from June 17, 2014, from iHealthBeat entitled, "Coalition Calls for Action Against EHRs That Block Interoperability." That gets, I think, Mr. Chairman, to the very point I am talking about. With that I yield back, Mr. Chairman.

Mr. PITTS. Without objection, so ordered.

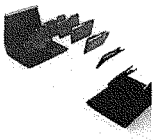
[The information follows:]

A SERVICE OF THE CALIFORNIA HEALTHCARE FOUNDATION

iHealthBeat
Reporting Technology's Impact on Health Care

Coalition Calls for Action Against EHRs That Block Interoperability

Tuesday, June 17, 2014



The Health IT Now Coalition is calling on HHS to decertify electronic health record systems that require extra modules or additional costs to share data, *Politico*'s "Morning eHealth" reports. The group also is calling on HHS and lawmakers to investigate firms that obstruct data sharing while participating in federal incentive programs (Gold, "Morning eHealth," *Politico*, 6/16).

Background

The calls come after a recent RAND Corporation report found that a lack of interoperability hinders technologies that otherwise could lower costs and improve care quality (Health IT Now Coalition release, 6/13). Specifically, the report found that Epic, an EHR vendor, was operating a "closed platform" that limited interoperability.

In response, an Epic spokesperson noted that the report was authored by two Department of Veterans Affairs researchers who suggested the VA health system's platform as an alternative to Epic's system ("Morning eHealth," *Politico*, 6/16).

Details of Call for Investigation

In a release, Health IT Now Executive Director Joel White said, "The RAND report reiterates what those in the health IT industry know well: Interoperability must be a priority if we truly want to improve patient outcomes, decrease costs and achieve a technology enabled system."

The coalition calls for HHS to:

- Work with lawmakers to investigate firms that could be inhibiting data sharing while being involved in federal incentive programs; and
- Revoke certification of EHR systems that require extra modules, expenses or other customization for data sharing.

White said that $24 billion in taxpayer money has been paid over the past three years to health IT systems that do not easily share data (Health IT Now Coalition release, 6/13).

Mr. GINGREY. And with that I yield back. Mr. Chairman, thank you.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentlelady from California, Mrs. Matsui, for 5 minutes for questions.

Ms. MATSUI. Thank you, Mr. Chairman. Thank you for holding today's hearing. It is been very, very interesting listening to all of you.

American innovation is transforming health care, integrating science, medicine and technology, to provide individuals with real-time access to vital health information, much of which was previously unavailable outside of a hospital or a doctor's office. Smart phones are really creating pathways for virtual interactions between doctors and patients. Texting between doctors and patients is becoming more common.

Now, telehealth is really at a critical juncture and increasingly becoming an integral component of the country's healthcare system. But one of the challenges of implementing telehealth is that there is no consistent standard. What we have is an inconsistent and often dated patchwork of State laws. States are currently considering passing legislation addressing telehealth policies which means there is a wide variation in how telehealth is defined and this inconsistency hinders the national deployment of telehealth, hurting those who need care the most.

And that is why I along with my colleague here on the committee, Representative Bill Johnson, introduced the Telehealth Modernization Act to create a workable definition for telehealth services. It provides a strong incentive for States to adopt consistent standards to remove the regulatory barriers to telehealth.

Now, you know, we move forward with all this, too, I am listening to all of this, and I want to ask the question here of Mr. Misener. You talked about some of the ways that cloud computing is enabling medical research, and I think that cloud technologies are useful to foster innovation and research.

And if we think really broadly, and I think about Amazon and all the data you have and all the information that you have and what you are doing now in the cloud, how can big data impact the healthcare sector and be expansive? And I would like to hear comments from the others, too.

Mr. MISENER. Thank you, Ms. Matsui. I think there are a dozen or so examples that I offered in my written testimony, but generally I think you are right on point that cloud services are an enabler of the biomedical field both in discovery and development but also in delivery, so I have tried to give you examples in each. But one way to think about this is a researcher today is typically constrained to thinking about questions that he or she may address only with the computing power that they have available in their laboratory, and so they can't think about big questions because they don't have much computing capacity.

But, if all of a sudden available to them on a temporary basis, however much or little they need, is computing power, they now can think about questions that are far beyond what their laboratory constraints impose upon them today. And so it really is an enabler of that discovery side of things, and it does again enable re-

searchers, scientists, doctors, to focus on what they are best at and not have to worry about the technology that enables them.

Ms. MATSUI. OK.

And Dr. Riskin, I would like your comments, too.

Mr. RISKIN. Sure. We are a big data company, so we see a lot of data.

Ms. MATSUI. Right.

Mr. RISKIN. One of our partners, a large health system sent us a million longitudinal records at one point recently and said we want to understand the association of concepts.

If you have a disease, diabetes, and you take a drug, is there any correlation with an adverse event there. We didn't have the processing power locally certainly to do that kind of effort. Fortunately we do work with Amazon and we have a good relationship with them, and we asked them can you spin up 100 servers and 20 threads per server, and can we have massive processing power, and we crunched away at the numbers for a day.

Ms. MATSUI. For a day.

Mr. RISKIN. Cross referencing every concept with every other concept. There is a challenge here, it is powerful. You get information that you may not want to have, and we work closely with the large academic centers to understand what information is useful and what information is not and put useful information out into the community. But there is a great responsibility behind that kind of work.

Ms. MATSUI. Absolutely. And would you be analyzing a lot of this data yourself, or are you going to, as you contract out with the other institutions, have them take that responsibility?

Mr. RISKIN. In terms of what gets published, we think it is best for the health systems, the large academic centers, to create protocols and publish, so we can crunch numbers and support them in their protocol. In terms of internal development, we certainly use information to develop the next products to influence patient care.

Ms. MATSUI. Do you see big data assisting in as far as the implementation as you get into the healthcare practices themselves down to the very ground level?

Mr. RISKIN. I hope so. I don't see that happening in the short term, a year or two, but I sure hope that happens in the long-term. It is one of the best approaches to reduce costs and improve outcomes in health care.

Ms. MATSUI. OK. I thank you, and I went over my time.

Thank you. I yield back.

Mr. PITTS. The Chair thanks the gentlelady.

Now recognize the gentleman from Ohio, Mr. Latta, 5 minutes for questions.

Mr. LATTA. Well thank you, Mr. Chairman, and thanks so much to the panel for being here. It is been a very enlightening discussion that you have all given us today.

And if I could start with Mr. Jarrin, in your written testimony, you stated that another important component of any 21st century technology for 21st century cures is spectrum, which is the lifeblood of our wireless networks. Mobile health solutions are part and parcel of an enormous surge in wireless data usage which is causing the spectrum crunch we are all now facing.

Now in this committee we have had many hearings, we have heard about the spectrum side and what is happening out there. One was that worldwide, by 2017, there would be 1.4 mobile devices per person across the globe. Well, that is not really going to happen because we know that in some areas of the globe of the technological challenges.

But I was also in another meeting the other day where they thought by 2017 in the United States alone there would be seven per person. So when you look at the numbers that are happening out there and also what you want to be doing with this whole technology, what can Congress be doing to help on this whole spectrum crunch to make sure that the technologies can advance in the future on your end?

Mr. JARRIN. Thank you. More spectrum is the lifeblood—spectrum is the lifeblood of mobile technologies and modern communications, modern wireless communications, and this committee and Congress in particular have actually shown a lot of leadership in trying to make more spectrum available. And when I mean spectrum, I mean licensed spectrum, shared spectrum, and unlicensed spectrum.

I believe recently there was a bill introduced to help make more sense of the five gigahertz spectrum. We welcome that. M health is not unique to any particular band of spectrum. It is just going to add to the spectrum crunch. There was a task force that was put together by the former chairman of the FCC a few years ago which I helped be a part of, and one of the findings of the task force was that through radiological imaging and videoconferencing, spectrum is going to be really even taxed more within the next couple of years because this is what is expected out of some of the systems and some of the services that we are discussing.

So the more that we have available spectrum, the better it is for the user because we are face a spectrum crunch. The FCC has been very honest about that. So it is something that we at Qualcomm take very seriously. We actually have an internal challenge where we are trying to maximize the use of spectrum 1,000-fold what we can today. Called the 1,000 X challenge, so I believe that Congress is really taking steps to do that, and thank you.

Mr. LATTA. Thank you.

Dr. Niloff, in the 21st Century Cures Initiative, the clinical trials process is one of the main focuses for the area, and, in my home State of Ohio, I have toured many of the premier research institutions across the State, and I have seen firsthand the important work that these individuals are doing to find cures for many different life-threatening diseases. Can you give us some examples of how these new technologies will assist with the clinical trial process and make it more effective and efficient?

Mr. NILOFF. Sure. So I think that the first thing that is sort of the lifeblood of any trial is the identification of appropriate patients who would meet the criteria, specifically have the disease that is to be studied, and by having patient registries, having patients' diseases codified as structured data in these electronic systems allows for the easy or more facile and rapid identification of the large populations of patients that you need as candidates for these trials. So

I think having that data available will expedite and increase the number of patients available for clinical trials.

The second part in clinical trials, is the ability to follow patients longitudinally and have good reliable structured data about the course of their disease and the different parameters of their disease to understand if the treatment under study is effective or not effective and by having an electronic source of that data that captures the patients clinical status and the response to the treatment under study in a repeatable, standard way, is very helpful in assessing the outcomes of the study and the conduct of the trials.

Mr. LATTA. Well thank you very much.

And, Mr. Chairman, I see my time is about to expire, and I yield back.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentlelady from California, Ms. DeGette, 5 minutes for questions.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

I really want to thank the panel for this excellent presentation this morning.

You might know that I am co-chairing this initiative with Chairman Upton, and oftentimes we have people come in and sort of talk vaguely about how great it would be to have a revision of the system, but you really came in with some specific suggestions, and we appreciate that as we look later this fall towards actually drafting legislation.

I just want to follow-up with whoever wants to answer this on some discussion we have been having about interoperability. Everybody agrees interoperability is important, and we are striving for that even now under the system that we have. We are making some progress, but I frequently meet with smaller companies as well as individual physicians who are talking about electronic medical records, and the concern that smaller companies have is that they really don't have the resources to work with patient data and to get that interoperability.

And I am wondering, Dr. Niloff, Dr. Riskin, and also Mr. Vockell, if you can sort of address what we can do to incentivize this kind of interoperability throughout the system, not just with the larger players who can afford to do it?

Mr. NILOFF. So I think that the solution to that is through collaboration, and it is not necessary for each individual company to reinvent the wheel multiple times, but through for instance the Commonwealth Collaboration that I referred to earlier is a mechanism where companies who might otherwise compete, be they large or small, can collaborate together and pool resources to develop technologies for interoperability that can then be broadly adopted.

Ms. DEGETTE. Do you think there is any governmental role in making those things happen, Doctor?

Mr. NILOFF. I think the Government role, again, at the end these solutions need to be paid for, and it all harkens back, if you will, to creating the economic environment and payment environment where the ultimate purchasers of the technology and the interoperability have a business case for purchasing it, which means aligning around a payment model, where having that technology makes

the providers successful in the payment model or care delivery model that they are operating under.

Ms. DEGETTE. Dr. Riskin, do you have a perspective on this?

Mr. RISKIN. Yes. Thank you. The question is a great one. There is a boundary between the electronic health record and the analytics system.

Ms. DEGETTE. Right.

Mr. RISKIN. When I work in the venture community in Silicon Valley, we look at opportunities, and there is very little coming through of new electronic health records. It is not where the new value is. The new value is in analytics and population health and patient engagement and we say for those companies to be successful, they need the data, so we will see company after company come in and say we are just going to have the data, and here is what we are going to do and we say that is not fundable because you can't get the data. It is too expensive.

So today, very expensive to get the data out. People are building custom interfaces into these electronic health records that is stifling innovation. There is a Government role here to say we paid for the data in the electronic health record, and here is the information we want out. Today's approaches have very limited information for analytics and population health, ignoring the compliance issues and social issues and other things, so actually requiring broad data to be brought out would be powerful to promoting innovation.

Ms. DEGETTE. Thank you. And Mr. Vockell, what about you? Do you have a view on this?

Mr. VOCKELL. Yes. Earlier Mr. Gingrey talked about Epic and their slow path to making their information available and at the other end of the spectrum is Allscripts which has made a lot of their data available to third-party developers and the challenge has been that I believe Allscripts and some of the other providers have been told here is the format and the type of data you need to make available.

And they look at their own system and they built it in an era that didn't anticipate making that data available and so it is hard work for them to build to this outside set standard, and it makes them not include stuff that Dr. Riskin would find very valuable.

A different approach could be you have to make your data in whatever format you currently have it available, and if you do, entrepreneurs will be all over building Rosetta Stones to translate it between the services. But since you are telling the slowest moving, ingrained, less hungry technology group to build to something, it is slow, and you know, Epic started a year and a half ago to build a public API, and it is barely out the door.

Ms. DEGETTE. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentlelady.

And I now recognize the vice chair of the full committee, Ms. Blackburn, 5 minutes for questions.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

And thank you all for being here. We do appreciate the panel.

The 21st Century Cures Initiative, the impact of technology in that is something that is incredibly important to our committee

and as you have seen from the questioning, we are working in a bipartisan way to address the needs that you all have, that patients have, and that the industry also needs.

And being from Tennessee, we have appreciated the convergence and the impact of technology on health care delivery and do feel like that some of the answers for not only health care delivery, but patient quality of life, are going to be achieved through these devices. And I know Mr. Green mentioned to you all the software act that he and I are working on. Ms. DeGette has joined us in this effort, and we feel is part of the backbone and that is necessary.

We are short on time. Votes are going to come up soon, so Dr. Niloff, I want to come to you and just have a couple of questions for you. The April 2014 FDAISA health IT report, are you familiar with that?

Mr. NILOFF. Yes, I am.

Mrs. BLACKBURN. OK. They have a framework that the ONC would among other things create a health IT safety working center. Are you familiar with that plan for regulating some forms of software and health IT?

Mr. NILOFF. Yes, I am.

Mrs. BLACKBURN. OK. All right, recently Chairman Upton and a couple of our colleagues and I wrote over to ONC to see where they think they are going to get this authority. And, have you seen that letter? Are you familiar with that?

Mr. NILOFF. I am familiar with it——

Mrs. BLACKBURN. We got a response recently, and we felt like that they really don't know where they have that authority, and like so many times agencies get into mission creep, and it concerns us.

We feel like the FDA wants to regulate our medical app products as medical devices, and they are not. And Congress in its infinite wisdom decided in 1996 to update the FDA statute by creating the definition of a medical device in order to differentiate it from drugs. Before that time there was no statutory difference between the two. So just like drugs, software is not a medical device. Medical devices are not drugs, and we think it is necessary to put some clarity in this structure.

So do you believe that Congress needs to get involved in the fix? Should we leave it to the FDA? Should we leave it to the ONC? Because it is beginning to us to look like a misguided system of regulation, and we don't want this to run off the rails. So I would like to know what your guidance and your thoughts would be on this.

Mr. NILOFF. So, when the Act was last updated, if you will, technology as we know it today did not exist, and I think could not even have been contemplated, so we live in a completely different technology environment today than when that Act was written. And I believe that the Act should be updated with the framework as described, a risk-based framework, so that we have clarity for the community, both today and clarity for the development community and the investment community going forward so we are in a stable environment that will allow for innovation and us to make good progress.

Ms. BLACKBURN. I thank you for that.

Mr. Chairman, I think it is just vitally important that the FDA and the ONC work with Congressman Green and I as we work with the committee to come up with what a structure is going to be so that all of our low and moderate risk items can proceed to the marketplace, and things that are invasive and high risk have the oversight of the FDA, and that clarity is provided for this Nation's innovators.

With that, I yield back my time.

Mr. PITTS. The Chair thanks the gentlelady. Now recognizes the gentleman from Louisiana, Dr. Cassidy, 5 minutes for questions.

Mr. CASSIDY. Dr. Riskin, I have got some weird experiences here, man. I go to a banker's office or a lawyer's office, and they have fewer clerical workers because of computers. I go to a physician's office, and they are hiring a data enterer and someone to train the data enterer because of computers. Clearly this is socking productivity.

Now, both of you, Mr. Vockell and Dr. Riskin, suggested that there is minimal investment and little incentive on the interface side of it, whereas there is a heck of a lot on the back side. That is wrong.

Now, when I speak to people, they wonder if the High Tech Act is not the problem; that by defining standards, we have stuck in amber certain systems, but as a doc, and I speak to docs whose productivity is down 25 percent, some of whom are taking the penalty. They are tired of looking at a computer screen instead of looking in a patient's eyes.

Do you agree with that assessment, that how the High Tech Act has been implemented is the—so to speak, we have met the enemy, it is us?

Mr. RISKIN. Thank you, Dr. Cassidy. I appreciate the question. Mixed agreement, in that the——

Mr. CASSIDY. Speak quickly, please, because I have only got 3 minutes now.

Mr. RISKIN. The High Tech Act was powerful in terms of getting initial information in electronically, that is definitely needed, but the current processes of requiring information in certain ways has been excruciating for doctors.

Mr. CASSIDY. So how do we unravel that?

Mr. RISKIN. Probably the way to unravel is through usability.

Mr. CASSIDY. Now, that is a little bit code for me.

Mr. RISKIN. Yes.

Mr. CASSIDY. When you say "usability," what do you mean?

Mr. RISKIN. The challenges, the doctor who is entering data right now, or their proxy, finds they are putting in information that isn't that useful, or they are being forced to put in information around billing that isn't clinically relevant. More of a focus on how can the systems be useable and how can we get the information——

Mr. CASSIDY. I get that. So there is an incentive apparently right now, I spoke of I am told it is stuck in amber. Entrepreneurs don't have any incentive to go in this space. Mr. Vockell just kind of suggested that. So what I am really asking is how do we once more incentivize these entrepreneurs to begin to do this as oppose—you know, get rid of the amber, so to speak.

Mr. RISKIN. So to solve the data usability problem, the data entry problem, the incentive would require that EHR's be usable and the EHR's would then need to work with companies to create usability. Right now there is——

Mr. CASSIDY. I accept that, but you can't just mandate from on high, Washington likes to think it can do so, make it useable. There has to be some penalty not doing so and there has to be some reward for doing so, not upon the doc, because the doc's already being penalized.

Mr. RISKIN. Agreed. And the physician community is less and less capable to push for useable systems.

Mr. CASSIDY. So, Mr. Vockell, what would you say to that, because you are nodding your head you are in agreement, but I am not sure I have understood yet how we get back to the entrepreneur in caring about this area.

Mr. VOCKELL. I think you have hit on what is the economic incentive. And right now there is no way for a doctor to translate, I could free up 25 percent of my time and see more patients or deliver a higher quality of care. And so if the payments that the physician were able to receive or the way that they were compensated was linked to the quality outcomes like——

Mr. CASSIDY. No. But, see, I am not making my point. The doc is willing to do this. The doc has taken the 25 percent hit. The doc is hiring the scribe at $12 an hour plus benefits. So I actually don't think it is the doc's problem; I think it is the vendor, if you will, who is not creating the interface, because they are either not required to or there is no reward. Why not just foist it off upon the doc as opposed to us taking the lumps. I mean, do you see my point?

Mr. VOCKELL. Yep. And I think they don't have the incentive, because there is such high switching costs to go from one system to another that——

Mr. CASSIDY. So how do we create that incentive?

Mr. VOCKELL. I think it is—I don't know how you will get an EHR to require to make their data interoperable, because that is the barrier to switching.

Mr. CASSIDY. Do you agree with the critic that says the way that ONR has instituted this program does stick in amber so that the companies like Epic can get high market share, but they have little incentive in order to create that better user interface?

Mr. VOCKELL. Yes. It makes them work towards the data center, yes.

Mr. CASSIDY. You agree with that?

Mr. VOCKELL. Yes.

Mr. CASSIDY. Let me ask one more thing. I read your testimony and didn't quite gather. You said there are strong economic disincentives for people to share data, but I didn't see you amplify that. What are those economic disincentives?

Mr. VOCKELL. So if you ask Humana to give you a data set around linked co-morbidities or protocols, it will cost you $500,000, because that is what they charged Pfizer for it. And so if you are a startup, or even a data analytics company who is trying to add a relevant data set that only payers have, you can only do it if you have got a half a million bucks.

Mr. CASSIDY. Gotcha. Thank you. I am out of time. I appreciate it.

Mr. PITTS. The Chair thanks the gentleman. Now recognizes the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman. And thank you to our panel.

Dr. Niloff, I am going to direct my question to you in the interest of time. We were just discussing—you know, kind of following up on some of the discussion, we were talking—I certainly see all the benefits to patients on health IT. You know, this really is an area that—of obviously much needed into the future, but there again, keeping in mind that we know that there are all the positives, what are the barriers? And I think we were just talking about some cost issues here for integrating the systems. Do you see this as an issue too, and are there other barriers that we need to be aware of?

Mr. NILOFF. Sure. So I think that the main barrier and the main challenge today as we have discussed is interoperability and continued innovation. And I think that we need to have the right payment model in place to drive the purchase of these systems. We need our delivery systems to have sufficient alignment of their different contracts that they are operating under so they are doing population health, coordinating care on a significant portion of their population, that they can make the investment both programmatically and technologically in these type of things, because that will drive innovation as the market grows.

Mrs. ELLMERS. And when you say "they," are you talking about the physician themselves or are you talking about——

Mr. NILOFF. I am really talking about at the health system level.

Mrs. ELLMERS. OK.

Mr. NILOFF. I think much of this technology, because physicians are now working in organized systems of care where they are part of an integrated network, and we are really driving to coordinate care from the in-patient arena to the outpatient arena, to long-term care, that really what we are talking about is health systems making purchases of technology, and not just electronic medical record technology, but enterprise registries to drive preventive care and manage patients with chronic illnesses, care management systems, where they use technology to identify high-risk patients and then have skilled nurses manage those patients, that those are the types of technologies and related programs that are ultimately really going to drive us to a delivery system which is going to drive real improvements in health.

Mrs. ELLMERS. So that would be, too—you know, just actually playing into another question, so I am just assuming that that is kind of the path that you see us taking as we are looking for the 21st century cures, and how we as legislators and here how we in Congress can help that effort, obviously you see that as an effort, too, when we are moving towards advancements in medical technology and curing disease and moving forward that way? Is that——

Mr. NILOFF. Yes. You know, I think that it would be helpful if, as Congress considers sort of health care for the 21st century, that

they think about health care in the context of not how we are delivering care today, but in a framework that thinks about the context of how we are going to deliver care in the future in a more optimal model; think about how we are going to have systems of care where everybody talks to each other, where when a patient moves from the hospital to a skilled nursing facility, their record moves with them, and it is not, you know—it is not—I am thinking about a family instance, but where, you know, an 80-some-year-old mother ends up having to be the major coordinator of care for her 93-year-old husband, because it is not happening electronically and the health system can't manage it.

And I think that what we have to think to is what sort of care model system of care that we are going to move to that makes it not just better care, but better experience for patients and families, and how Congress can modify the law to drive that type of system of care, which will benefit all Americans.

Mrs. ELLMERS. Thank you, Dr. Niloff.

And thank you, Mr. Chairman. I yield back the remainder of my time.

Mr. PITTS. The Chair thanks the gentlelady. And now recognizes Mr. Butterfield, 5 minutes for questions.

Mr. BUTTERFIELD. Thank you very much, Mr. Chairman. And thank all of the witnesses for their testimony today. I want to commend you, Mr. Chairman, for the subject for the hearing today, 21st century technology for 21st century cures. I like that, and I hope that as the session that moves along this year, we can continue to develop some ideas.

To all of the witnesses, and I can't call on each one of you, but whoever feels the most comfortable, I would ask that you respond. We know that certain population segments, including seniors and Americans with disabilities, are less likely, less likely to adopt broadband at home. Do the broadband enabled innovations that we have discussed today help these Americans get online and receive all the benefits of the applications we are discussing today?

That is not fair to you. I guess I should have called on one or two, but let's do it this way, and then I will call on someone next.

Mr. JARRIN. Sure. So the answer to big data, you know, when we are talking about big data, and I hear the theme coming up quite a bit today, part of that is connectivity. Without connectivity, there is no real big data, whether it is wired, wireless or mobile. Increasingly, it is becoming mobile, and that is obviously represented in the figures I gave at the beginning, 355 million users in the U.S., 7 billion in the world.

So I believe that through, you know, products like those of Amazon, products like the chipsets that Qualcomm produces and go into those products, those consumer facing devices, et cetera, they are getting out there. I believe the FCC quoted that over 95 percent of the country is now covered by at least one mobile broadband provider. More needs to be done, both on spectrum. Also I know that the FCC is working hard towards reaching disparate populations through their rollup broadband program, but I believe that we are getting there. We are getting there.

Mr. BUTTERFIELD. All right. We have a buzzer to go to the floor, so I will just ask one more, Mr. Chairman.

Telehealth programs are critical to communities in rural areas like my district in eastern North Carolina. East Carolina University, for example, has set up a telehealth opportunity at clinics throughout many rural communities that enable constituents to receive specialized medical care without traveling long distances. And I know all of you are familiar with this and you are looking forward to the next generation of technology.

What are the major challenges, such as broadband access, that rural communities face in fully utilizing telehealth opportunities? If each one of you could just do a couple of sentences, starting with Mr. Vockell.

Mr. VOCKELL. Well, I think probably they are more qualified down there, but I think mobile devices are beginning to take over what that capacity is. It is less, you know, cables into the home and it is what used to be wired is now wireless. So as the Qualcomm guys continue to do their good work and 1000X the bandwidth.

Mr. MISENER. If you wanted me to answer, Mr. Butterfield.

Mr. BUTTERFIELD. Sure.

Mr. MISENER. Mr. Jarrin is exactly right. Connectivity is the key. And we have always heard, at least for the past two decades, that telehealth was going to be a major driver of the need for connectivity in rural areas, and now it is here. So I think the concept of ensuring broadband deployment nationwide, including in rural areas is extremely important, not just for telehealth, but especially for it.

Mr. RISKIN. The answer, from my perspective, I actually have an appointment in a safety net hospital. I am very familiar with the access issues that occur. And I would say connectivity is critical, but patient engagement is just as difficult. Whatever modality you are using to reach your provider, if the patient isn't engaged in their care, and typically rural or safety net communities are more difficult to engage, they won't be able to work with that modality.

Mr. JARRIN. And I know that we are almost out of time, but one thing that I would like to mention: So Qualcomm sponsors many things. We have a program called Wireless Reach. One of our recent projects was delivering care in a Native American area near Flagstaff, Arizona. And there were issues with being able to get mobile broadband in those areas. There was no connectivity whatsoever, but there were—there was one operator in particular that actually was able to reach this population. And what we did was we provided telephones, mobile, smart phones that connected with home use medical devices such as medical grade weight scales and blood pressure cuff monitors. And what happened was that a person with congestive heart failure would use these devices, it would connect with the smartphone, go into the hospital, and then a series of nurses and other care providers would actually develop a work flow and be able to inform the patient of when things were going badly. We were able to reduce hospital readmissions through that very well.

Mr. BUTTERFIELD. The chairman is tapping on his microphone. That is our——

Mr. JARRIN. Unlimited broadband is a very important thing for——

Mr. BUTTERFIELD. I get it. Thank you.

Mr. PITTS. The gentleman has time expired. We are in the middle of a vote. We have got 10 minutes left. We are going to try to finish here. Mr. Griffith, you are recognized 5 minutes for questions.

Mr. GRIFFITH. Thank you very much, Mr. Chairman.

Thank you all. This have been a very educational hearing. As you can hear, there is bipartisan support for trying to figure out how we go forward. I have heard all kinds of things. You know, figuring out the payment model when we are using new devices that you may not even have to go in to see the doctor on and electronic health records.

My concerns parallel those of Ms. Blackburn when she talked about devices. It was sometime a year, a little over a year ago, we had an FDA representative in here, and I asked them about this $8 hack that had been used in Africa to send photographs to a hospital in the United States. You had a team of Canadian and I think Swiss doctors working on it, and they were able to identify a parasite out of the stool of children and get a diagnostic fix figuring out which parasite it was and do the treatment the next day. I said, would this be a medical device? And the answer was, yes. If it is diagnostic, it is a medical device, even though all they were doing was taking a picture on a smartphone with an $8 hack. Because it was being used diagnostically, the FDA thinks it is a medical device.

So I think it is very important that we pass language that we can approve in a bipartisan way that clears that up so that, as she said in her statement earlier today, if it is a truly—you know, something that is invasive, we want FDA making sure it is safe, if it is just diagnostic, we want to make sure that we get it to the market.

And, Mr. Jarrin, I noticed, and it is in your written testimony and in your oral testimony, you mentioned like 15 devices that you could use that would give you some diagnostic capabilities without the healthcare provider being present. Are you all finding that FDA's worried about that or spending a lot of time on that?

Mr. JARRIN. Well, actually the X PRIZE included the FDA originally, so that way we wouldn't land into those issues and lack that clarity, because that was definitely an issue that we were considering, whether or not this would be obviously a medical device. So the FDA joined the project early on. I believe that Dr. Shuran, who may have been the person that you were referring to, actually even put a video on the FDA Web site about their involvement with the X PRIZE. So I am hoping that when everything is said and done, you know, we will all be on the same page.

One thing that I would mention, you have an excellent example of the kind of clarity that was needed and still needs—there is never enough, right?

Mr. GRIFFITH. Right.

Mr. JARRIN. Because that exact example is something that they actually ended up putting into the draft—the final guidance by saying that those mobile apps that can be used to visually augment, you know, whatever a provider is dealing with in a diagnosis would not be regulated under their enforcement discretion. So, you know,

it was very helpful. Again, Congress was very helpful, because when you ask those questions, I believe the agencies really do pay attention and listen, and the FDA in that very specific instance did exactly that. You know, they did release the mobile medical apps guidance document. I believe that FDASIA tries to deregulate 95 percent of what they—what they say very specifically, most CDS products and mobile medical apps and health IT software, but now it needs to be codified.

Mr. GRIFFITH. I might need to cut you short, because I have got to leave a little bit of time for Mr. Bilirakis to get a question or two in.

I would say that not only is that important, I am glad that they were listening, but the telemedicine is going to be very important. I represent a rural district, and it is going to be extremely important in the rural parts of this country.

Thank you so much. With that, Mr. Chairman, I yield back.

Mr. PITTS. The Chair thanks the gentleman. Now recognize Mr. Bilirakis. 5 minutes for questions.

Mr. BILIRAKIS. Thank you. I appreciate it, Mr. Chairman. And thank you, Mr. Griffith, for keeping it short. I really appreciate it. I want to go quickly, too.

With regard to the cloud, unfortunately, 10 percent of the agencies who adopt the cloud in the Federal Government, so it hasn't really been a success on the Federal level, unfortunately, but in the private sector, the private sector has rapidly adopted cloud-based solutions. And I know Representative Matsui actually touched upon this, but I have a couple questions.

What are some of the barriers to the adoption and expanded use of cloud-based computing and cloud-based storage in the medical space, and how can we facilitate the expanded use of cloud? What are some of the laws that need to be examined, because of the way they interact with the cloud computing?

And anyone on the panel can respond. Doctor?

Mr. VOCKELL. The cloud expert to start, probably.

Mr. MISENER. Well, thank you, Mr. Bilirakis. I appreciate that. In our experience with Amazon Web Services, the take rate isn't as great as we would like it to be with Government agencies, but it is changing, and as I mentioned in my testimony, we already serve many around the world, but in the Federal Government, there are areas where Congress could lead by example, either through legislation or working in their oversight role over agencies to ensure that agencies do use cloud when it makes sense to.

Right now, sometimes agencies feel constrained to buy only traditional hardware and software and pay their own in-house people to run it, and that turns out to be highly inefficient, and so hopefully Congress, through the two acts that I mentioned in my testimony, including FITARA, could encourage the Government use of cloud, to the benefit of our taxpayers, of course. Thank you.

Mr. BILIRAKIS. Anyone else on the panel? OK. I will get on to the next question.

With regard to the medical devices in the dialysis world, they have remained largely unchanged, you will agree with that. If you were to need kidney dialysis, you would basically be using the same devices your parents were using. There have not been any

large innovations in that space. However, in the world of consumer electronics, there have been continued innovations in this space. Televisions today are radically different from televisions in the 1990s, cell phones today are different than they were, the ones in the 1990s, tablet PCs are different than the laptops and notebooks from the past decade.

So my question is, How is it that we can have rapid innovation in consumer electronics with lower costs for consumers, but slower innovation with higher costs in the medical space? Is it the cost of the excessive regulation? Is it the higher barrier to entry? How do we encourage shaking up the status quo?

And whoever would like to begin, please.

Mr. JARRIN. I actually will take it only because I am aware of a pilot project that is actually part of the Center for Medicare and Medicaid innovation challenge grants which is being conducted at the George Washington University Hospital in consult with a company named DeLier and a company named Baxter and a number of other partners, and it deals with kidney dialysis in one way or another. So I believe that that community is definitely listening. They are really looking into things like remote patient monitoring, et cetera.

But if I step back for a moment, I think one of the largest barriers to adoption for this entire field are the outdated rules that we have governing reimbursement for services, particularly when we talk about remote patient monitoring, it automatically gets lumped into something called telehealth reimbursement, and it is not necessarily the same thing. Under the telehealth rules, you have to start off from an originating set of care that CMS stipulates; it has to be a specific disease condition, there is only about 20 or 25 of them; and it can't happen in a metropolitan statistical area, it has to happen in a health shortage area; it has to be live voice and video, which removes automatically all the stuff that we are working on. It is incredibly restrictive.

So according to the American Telemedicine Association, doctors are only able to access between 5 and $8 million—with an M—worth of reimbursements for telehealth consults. You know, the CMS budget is near $800 billion, so I would pause to think that some of that could by targeted towards incentivizing the uses of these types of equipment and services, because the issue is this: If I am a hospital or I am a health plan, if I am not being reimbursed by my largest population, which happens to be Medicare, I am not going to be incentivized to adopt those technologies that I am not being paid to use, or to provide services that I am not going to be paid to provide.

So I think that is a real huge barrier to adoption. And then that folds into, of course, the incentive payment program, which has done a good job of incentivizing the use of electronic health records, but there is no aspect that actually allows for patient-generated health data to go into that electronic health record, so the patient is really literally cut out, except when he walks into the facility, and then you have got the situation that your colleague was mentioning where we have the scribe, you know, typing stuff in while the doctor and the patient discuss their care. So it is a real complex issue, but I think that I those are barriers to adoption.

Mr. BILIRAKIS. Thank you very much. Thank you, gentlemen, for your testimony.

I yield back, Mr. Chairman.

Mr. PITTS. Thank you.

Thank you again to the witnesses for sharing your expertise. This has been a very informative hearing. I am sure members will have a lot of follow-up questions. We will submit those to you in writing. We ask that you please respond promptly.

I remind members that they have 10 business days to submit questions for the record. Members should submit their questions by the close of business on Thursday, July 31st.

Another very important, informative hearing. Thank you very much. Without objection, this subcommittee is adjourned.

[Whereupon, at 12:21 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

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Majority (202) 225–2927
Minority (202) 225–3641

September 3, 2014

Mr. Dave Vockell
Chief Executive Officer
Lyfechannel
180 Glasgow Lane
San Carlos, CA 94070

Dear Mr. Vockell:

Thank you for appearing before the Subcommittee on Communications and Technology and Subcommittee on Health on July 17, 2014, to testify at the joint hearing entitled "21st Century Technology for 21st Century Cures."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, September 17, 2014. Your responses should be mailed to Charlotte Savercool, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Charlotte.Savercool@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Greg Walden
Chairman
Subcommittee on Communications
and Technology

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Communications and Technology
Frank Pallone, Ranking Member, Subcommittee on Health

Attachment

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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Minority (202) 225–3641

September 3, 2014

Mr. Dan Riskin
President
Health Fidelity
459 Hamilton Avenue, Suite 205
Palo Alto, CA 94301

Dear Mr. Riskin:

Thank you for appearing before the Subcommittee on Communications and Technology and Subcommittee on Health on July 17, 2014, to testify at the joint hearing entitled "21st Century Technology for 21st Century Cures."

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Post-hearing Questions

Testimony of Dan Riskin

Committee on Energy and Commerce Subcommittee on Communications & Technology and Subcommittee on Healthcare

Questions from the Honorable Joe Pitts

1. The characteristics of big data - Velocity, Variety and Volume - are often minimized when used for healthcare due to the complexity and restraints of HIPAA. Does Congress need to take a fresh look at our privacy laws to enable patients to become "data donors", giving consent to allow their medical data to be shared for longitudinal research.

This question strikes at the heart of how clinical data can be valuable not just for daily patient care, but also for making the practice of healthcare more effective and efficient. Congress could significantly benefit the nation if it took a fresh look at privacy laws to examine how patients can be empowered to consent to specific uses of their data to advance medicine.

The big data opportunity to advance the practice of healthcare is powerful. Based on direction from Congress, an immense quantity of clinical data is now being collected. There is an opportunity to mine these data to understand more effective and efficient clinical approaches that leverage clinical observations, genetic information, consumer biometrics, and consumer observations. Research has been

hindered by inability to consistently extract full clinical data from the electronic health record (interoperability) and inability of patients to consistently authorize use of their data for such research (consent). Each issue will be discussed in turn.

The interoperability requirement to make big data effective for research is a business problem. Given that most data are currently not required to be interoperable from the EHR itself, each health system must independently pay to build custom interfaces to translate portions of the medical record. At a business level, the cost of custom data interfaces is acceptable in certain circumstances and for some data, specifically where it influences the top or bottom line of the health system. An example is extraction of portions of EHR data relevant to and that can support billing optimization. On the other hand, the clinical data needed for research are far more extensive and the business drivers for research are less robust. For example, a study may require testing two interventions against an outcome such as an adverse event, improved symptom, or worsening of disease. Many of these outcomes do not exist as interoperable data, but rather require big data techniques applied to shared full clinical data, including discrete and narrative content on an encounter-by-encounter basis. Thus, within today's federal interoperability requirements, it would be exceedingly expensive and would not make sense for a health system to pay for extraction of the expansive clinical data that could accelerate research. Even interoperability requirements being considered for Meaningful Use Stage III will not be sufficient, as the patient summary represents a tiny fraction of the full clinical data captured in the EHR.

An interoperability mandate that could meaningfully support big data research in healthcare would need to include interoperability of full clinical data.

The consent requirement to enable big data research in healthcare is primarily a logistics challenge. There is currently no consistent approach or guidance for how to safely and consistently garner patient consent for needed research that leverages electronic clinical data. There is no health system that can afford the logistics required to request consent from each patient for each potential question. Similarly, the logistics of meeting multiple privacy and security regimes imposed by the states in addition to those included in HIPAA create an overwhelming data challenge. While the interoperability needs are clear (though not yet addressed), the pathway to support safe and consistent consent is far less clear. Congressional review of approaches to allow safe and consistent use of clinical big data, including potentially identified or re-identifiable patient data, would be a boon to the research world and could greatly expand the value derived from clinical data being captured today.

2. What are the barriers to deploying genomics data into clinical care? When can we expect to see the ultimate big data incorporated into Electronic Health Records to enable personalized medicine to replace many of the trial and error treatments patients receive today?

One of the most powerful uses of clinical data to tailor and improve care will be

integration of clinical and genomic data. Early successes have already been seen in this field.

While the EHR is well set up to capture clinical data at the point of care and to support hospital workflow, these key features reflect a core competency and the majority of spend of EHR companies. Other firms have greater expertise in robust data analytics, genomic integration, or consumer engagement. Just as consumer internet software must frequently interact with other software to be effective, a phenomenon often referenced as "apps," so must health IT advance beyond monolithic software built by one company and upgraded annually.

In a future world, the clinical phenotype (or clinical characteristics of the patient) will be collected by the EHR and the clinical genotype (or genetic characteristics of the patient) will be collected by a lab system. Perhaps consumer information (such as biometrics) is captured by a watch and uploaded to another cloud repository. These data sets can be powerfully integrated to understand relationships of diseases, impact of treatments, and opportunities for intervention. The data needed for these types of analyses are collected today.

There are multiple barriers to combining genomic data with clinical data sets to better tailor therapy.

- Cost: The primary barrier for many years has been cost. Today, basic genetic evaluation with single nucleotide polymorphism (SNP) is simple

and cheap, and full genetic mapping is rapidly becoming available and affordable. This barrier will rapidly disappear based on market forces.

- Interoperability: The next challenge is combining the genetic data with phenotypic data. This cannot be done within the EHR as those systems are being given incentive for deployment, workflow optimization, and maximized reimbursement. It is unlikely that any federal program will give sufficient incentive to the EHR firms to focus meaningful innovation outside of their core areas. Thus, other firms must be given the opportunity to combine and analyze these data sets. Interoperability will be required for emerging software to access the clinical phenotype of the patient. Billing data and patient summaries will not be sufficient, so national interoperability aspirations will need to change before progress can be made.
- Incentives: There is limited incentive to tailor therapy in a fee-for-service world. In its current manifestation, value-based healthcare supports measurement of quality, but gives limited incentive for the multi-year efforts or for the significant infrastructure spend that personalized medicine will require. The payment model would need to actively support tailored therapy, through hospital, professional, and diagnostic reimbursement.
- Privacy: Current privacy policy does not support the patient in consenting to the research and clinical approaches that personalized medicine will require.

3. You state in your testimony that "data-driven healthcare not only assures the right information is available for the right patient at the right time, but also provides pathways for information to be used in less traditional ways, such as population health and patient engagement. In your opinion, what barriers currently exist that this committee and the general public should keep in mind when thinking about the potential of data-driven health care? For instance, some previous witnesses have stated that while the intent of HIPAA is great, it has become burdensome in some areas and actually prohibit the kind of patient empowerment and interaction that we all believe is necessary. Are there others?

To be implemented in the real world, data-driven healthcare requires a combination of technology and workflow.

There are drivers and there are barriers that significantly impact the pace of adoption. The greatest drivers for data-driven healthcare are reimbursement for care improvement, subsidized collection of data, and increasingly powerful technology. The greatest barriers for data-driven healthcare are limited consumer engagement, limited physician incentive to improve care, strong physician disincentive to expend unpaid time on new technology, limited data interoperability, complex privacy policies, and poor alignment of payment incentives. Too often, those who hold patient information see it as a competitive advantage instead of a resource for improving care for all.

While many factors are outside of the scope of Congress, the committee may consider foundational issues of privacy, interoperability, and payment incentives if the goal is to support a more rapid transition to data-driven healthcare. Privacy and interoperability are discussed in previous questions. Payment models are being considered in depth by CMS. One overarching challenge remains the annualized view of payments that restricts personalized and population health efforts that may provide extended benefits over years. These benefits, because of timeframe of benefit, are often not captured by the health system that is asked to invest.

4. You state in your testimony that "through the meaningful use program, our country has footed much of the cost of electronic capture of clinical data." Then you go on to ask "Why wouldn't we require that all data we capture be available for use by innovative companies and technologies that improve care." Can you expand on this idea? Are there barriers that currently prohibit such sharing?

The federal government has subsidized massive expansion of a segment of the healthcare information technology (HIT) industry. This segment, electronic health records, is only one facet of the HIT solution. In fact, analytics and workflow design, which have the greatest potential to influence costs and quality of care, were rarely mentioned in early years of national spend on HIT and are only now coming into the national spotlight. The EHR is important mostly in its ability to feed downstream systems and has done its job well in capturing electronic data.

In an ideal world, the data captured by the EHR would then be shared between software systems so firms with the greatest expertise in areas like population health and patient engagement can compete on equal ground. But, with government funding, the EHR segment finds itself extremely well-funded and in need of expansion opportunities. EHR companies are considering expanding into population health, clinical analytics, disease management, consumer engagement, revenue cycle, and many other areas of healthcare. While other companies may be more expert, they are frequently locked out of the market based on the expense of drawing data out of the EHR. There is a strong financial incentive for EHR companies to prevent easy and efficient access to data, thereby creating data lock in and a competitive advantage across multiple industry segments.

The government has created this challenge through preferential subsidies to one market segment. The data now exist within one set of software systems. Only the government can change policy to require the data be available for other businesses to create products which play to their strength and to recreate an environment of competition.

There is widespread recognition that interoperability should be required, but limited discussion within congress of what specific interoperability is needed. Current focus of discussion is on sharing of patient summaries. This solves a problem known as transition of care. Specifically, if a patient goes to a health

system for care and a different emergency department for an urgent condition, both systems should have the same background clinical information. This problem is obvious and should be solved. But, the more pressing and far reaching problem is that of clinical analytics and population health. This is where the predominant financial benefit in health IT is to be found. Unfortunately, patient summaries provide minimal support for clinical analytics and population health. As an example, a software system may seek the high risk patients that are likely to be readmitted to the hospital and could benefit from resources at home. A physician narrative on follow up clinic visit may state, "This gentleman appears frail and malnourished. He is poorly compliant with his medications as he has been unable to find transport to the pharmacy to have medications refilled. He is coughing profusely." While this is all critical information for population health and all of it would exist in the EHR, absolutely none of it would be included in a patient summary and none of it would make it to the software system used for population health. A patient summary includes a few data elements such as a problem list and a medication list, but ignores content such as social situation, clinical impressions, and risk factors.

So, in fact, congress paid for capture of massive amounts of clinical information, but only asked that a tiny portion be shared with analytics software and other systems that can influence cost and outcomes. With current Meaningful Use Stage III proposals, only a modest portion of information would be shared and available for analytics. Sharing of full clinical data is feasible and needed, but only sharing

of patient summaries is being requested.

The Honorable Anna Eshoo

1. What are your top two policy recommendations that Congress could undertake to improve the adoption of telemedicine?

Telemedicine offers great promise. Potential benefits of telemedical consultation include: reduced costs, reduced patient wait times, better patient experience, more effective triage and use of primary care, better and more immediate access to practitioners of appropriate training and skill, and more efficient team-based medical approaches. Advanced telemedicine platforms currently incorporate secure and private high definition audio and video capabilities, file sharing between patients and doctors, and access to a robust network of physicians.

Few of the challenges in telemedicine are related to technology. Rather, a host of barriers exist related to: reimbursement models, physician licensure, ambiguity regarding the appropriate scope of and standard of care for telemedicine visits, uncertain legal exposure in telemedicine visits, and lack of experience in telemedicine to define best practices.

Telemedicine is desirable for the consumer and can support an efficient health system. Thus, there is a strong national incentive to lower barriers to provision of

telemedicine and support financial viability of virtual care.

There have been extensive discussions on ways to support telemedicine. Two efforts Congress may consider to promote adoption of telemedicine are: (i) guidance to Centers for Medicare & Medicaid Services (CMS) to pilot reimbursement models that support telemedicine and (ii) further legislative definition of acceptable telemedicine practice including standardized telemedical licensure in each state.

Additional areas to consider include approaches to reimbursement for primary and specialty-based virtual care, the Federation of State Medical Boards Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine, and approaches to minimize licensing barriers for physicians that are no longer as geographically tethered as they once were.

2. What are additional steps we can take to encourage interoperability with electronic health records, while ensuring patient privacy and HIPAA standards?

Interoperability is required to support safe transitions of care and to support future needs in clinical analytics and population health. The challenge is that the more data is shared, the more data is at risk. A robust network of electronic usable patient data must be balanced by equally robust privacy and security protections.

To enhance interoperability, requirement of full clinical data sharing should be considered in Meaningful Use Stage III. Sharing patient summaries is simply not sufficient to support clinical analytics and population health.

As data are shared between systems and potentially stored in multiple local and cloud repositories, risk for data breach increases. HIPAA offers robust approaches for managing a data breach once it has occurred, but offers little guidance on preventing the problem. Breach prevention will become increasingly critical as clinical data is increasingly moved and used.

The fact is that we are in a new world of cloud systems and expansive electronic patient data. Best steps in privacy and security are not necessarily clear, so the best answer to the question may be a rational approach to solving the problem rather than a simple solution.

In considering privacy and security legislation, the following broad issues should be seriously considered: Inconsistent security protocols in cloud storage of identified clinical data, failure of health systems to universally require data encryption at rest for data stored behind firewalls, inconsistent encryption of data in transit, different standards of security at the health system level for clinical data used in operations versus clinical data used in research, inconsistent approaches to patient consent for use of data, and limited sophistication in data access privileges

and controls within covered entities and business associates. These challenges are complex and new.

FTC Commissioner Julie Brill has noted that consumer generated health information is growing, through connected devices and the Internet of Things, with health data flows that are occurring outside of any medical context, outside of HIPAA and outside any healthcare regulatory regime. HIPAA has always been a limited scope security and privacy rule. Potential revision should consider the gap where various entities collect or maintain healthcare data but are not covered by the HIPAA Rule. There are significant changes in technology, data, and hospital workflow from what existed even a few years ago.

Finally, consideration should be given to expanding what is considered identifiable. Consistent application of best practices and common policies will help build trust. Patients continue to be concerned with data privacy, and this includes both healthcare and non-healthcare data. Hospitals in many cases must comply with many different requirements including HIPAA, SOX, PCI, and numerous state privacy, security and breach notification laws. An approach focused on overall privacy, security and breach notification requirements for all personally identifiable information (PII), and not just PHI, may be beneficial, expanding from a sectoral approach toward an overall security posture. This may, over time, reduce compliance uncertainty for organizations that are awash in expanding data flow and increasingly complex data use opportunities.

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September 3, 2014

Mr. Paul Misener
Vice President, Global Public Policy
Amazon
126 C Street, N.W., 3rd Floor
Washington, D.C. 20001

Dear Mr. Misener:

Thank you for appearing before the Subcommittee on Communications and Technology and Subcommittee on Health on July 17, 2014, to testify at the joint hearing entitled "21st Century Technology for 21st Century Cures."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Frank Pallone, Ranking Member, Subcommittee on Health

Attachment

Questions for the Record – Responses from Paul Misener, Vice President, Global Public Policy, Amazon

The Honorable Joe Pitts:

Q 1. You mentioned the CDC's use of cloud for providing awareness for health-related threats and to support responses to these threats – how has the cloud strengthened our emergency response system to maximize our emergency operations health care delivery system?

More details about Amazon's work with the CDC are available here: http://aws.amazon.com/solutions/case-studies/us-centers-for-disease-control-and-prevention/

With the organization's BioSense 2.0 program, the CDC is tasked with providing awareness for all health-related threats and to support responses to these threats at the national, state, and local level. Needing to avoid purchasing expensive hardware and software, the organization turned to AWS for its low cost, pay-per-use model of cloud computing services, which has helped to enable this system with high availability and security, and improved agility.

Q2. Are there other nations that have utilized the cloud for their research? What could this mean for working with other nations and global clinical trials?

There are over 800 government agencies and 3,000 educational institutions worldwide that currently leverage cloud computing services from AWS. One example is how the Centre for Software Practice (CSP) at the University of Western Australia is leveraging cloud services to enable research into the impact of technology on online communities, open source development, and health informatics, at a much lower cost. More information is available on this case study here: http://aws.amazon.com/solutions/case-studies/university-of-western-australia/

Q3. Are there any laws or regulations that have impacted the development of cloud?

As suggested in my July 17 testimony, Congress could work with the Department of Health and Human Services (HHS) to modernize implementation of the Health Insurance Portability and Accountability Act (HIPAA) so that healthcare providers can readily employ the benefits of cloud computing without any compromise of the strong privacy protections HIPAA now affords health information.

Q4. Amazon worked with the FDA to turn 900,000 hand written reports of adverse drug effects each year into machine-readable information with 99.7 percent accuracy, reducing costs from 29 dollars per page to 25 cents per page. This cures initiative is in part focused on using technology to relieve administrative burdens for agencies such as the FDA so they can use those resources to invest in more researchers or new development methods such as biomarkers.

Do you have suggestions for other ways we can increase the efficiency at the FDA and other agencies?

One area where CIOs should be given more authority and flexibility is with respect to spending models, specifically capital expenditures (CAPEX) versus operating expenditures (OPEX). Given that much IT hardware and software has only a three-year lifecycle, agencies should be allowed to place capital funds into "Working Capital Funds" that preserve the funding for the agency to pay in multiple

years for cloud computing services based on what they actually use. The current "use or lose" approach is a disincentive to saving money. Agencies should shift to paying only for what they use in OPEX, versus spending in CAPEX to stockpile servers, software, etc., because their budgets expire at the end of a fiscal year.

Also, to help accelerate the discovery and development of new biomedical treatments and cures, Congress could enact H.R. 967, the Advancing America's Networking and Information Technology Research and Development Act (one section of the bill would require an assessment of how federal science agencies can facilitate the use of cloud computing for federally-funded science and engineering research).

How can we modernize HIPAA to ensure that patient information is protected but we can utilize data?

Amazon fully supports the need for strong protection of the privacy and security of health information. However, there are areas where the HIPAA statute and regulations are a poor fit for cloud computing services. For example, the HHS Office for Civil Rights indicated that a cloud provider is subject to HIPAA as a "business associate," even where the information is encrypted and the cloud services provider does not have the decryption key. This impedes health care entities from leveraging the cloud, causing the parties to negotiate a "business associate agreement" in which virtually all of the terms are inapplicable because the cloud services provider does not have access to the information. Additionally, the HITECH Act provides that an entity is subject to substantial HIPAA penalties even if it did not and reasonably could not know of a HIPAA violation. HHS has broadly interpreted that an entity becomes subject to HIPAA when they maintain protected health information on behalf of a HIPAA covered entity, regardless of whether they agreed to do so in a business associate agreement or otherwise.

Congress can play a critical role in facilitating health care's greater use of cloud computing services by addressing some of these regulatory challenges, including excepting from HIPAA entities that: (1) maintain encrypted information but do not have the technical ability to access the information; or (2) have received no notice that they have received HIPAA-covered health information. By narrowing the application of HIPAA to situations where the cloud provider has access to the information and knowledge of the information, parties can avoid wasting money on contracts that are mostly inapplicable and cloud service providers can more reasonably comply with HIPAA by focusing on areas where they have been informed that health information resides.

Q5. How should we encourage academic researchers to utilize the cloud? What are the reasons researchers wouldn't want to utilize the cloud?

Congress could work with the National Institutes of Health (NIH) to establish and operate cloud-based data management platforms, which federally funded researchers could use to share their data. If federal funding agencies, such as NIH, established and operated cloud-based data management platforms, federally-funded researchers would simply upload their research data along with any relevant software resources required to reproduce their analysis of the data. Other researchers in the field could then access the data and software in order to reproduce results, re-analyze previously collected data in novel ways, or even automate the analysis of new data using the same approach as the original

experiment. This would result in the elimination of costly and unnecessary duplicative research and thereby accelerate the pace of biomedical discovery.

More and more researchers are using AWS and our pay-per-use model of cloud computing services and are significantly lowering costs and enabling greater innovations in the process. However, one challenge that federally funded research organizations and researchers still face is that the federal funding process still enables more capital expenditures (CAPEX) then operational expenses and significant amounts of research dollars are allocated for hardware and software expenditures or related overhead costs. If there is more emphasis by federal researching funding agencies on the use of cloud computing services via operating expenditures (OPEX), recipient organizations can spend less on capital expenditures to buy equipment and can invest more on the actual research.

The importance of the utility-based model of cloud computing on Page 41 of the President's FY2015 Budget Request:

Expanding Federal Cloud Computing.

The Budget includes investments to transform the Government IT portfolio through cloud computing, giving agencies the ability to purchase IT services in a utility-based model, paying for only the services consumed. As a result of the Administration's Cloud First policy, Federal agencies adopting cloud-based IT systems are increasing operational efficiencies, resource utilization, and innovation across the Government.

The Honorable Joe Barton

Q2. Please provide us with examples of how we can "modernize" the implementation of HIPAA? Are you suggesting weakening the law or creating some sort of loophole as it relates to privacy? Please provide examples of when cloud-computing services would not have access to, or knowledge of, the information stored on their services and would therefore have no responsibility as relates to any sort of breach of data or security vulnerability?

Amazon fully supports the need for strong protection of the privacy and security of health information. However, there are areas where the HIPAA statute and regulations are a poor fit for cloud computing services. For example, the HHS Office for Civil Rights indicated that a cloud provider is subject to HIPAA as a "business associate," even where the information is encrypted and the cloud services provider does not have the decryption key. This impedes health care entities from leveraging the cloud, causing the parties to negotiate a "business associate agreement" in which virtually all of the terms are inapplicable because the cloud services provider does not have access to the information. Additionally, the HITECH Act provides that an entity is subject to substantial HIPAA penalties even if it did not and reasonably could not know of a HIPAA violation. HHS has broadly interpreted that an entity becomes subject to HIPAA when they maintain protected health information on behalf of a HIPAA covered entity, regardless of whether they agreed to do so in a business associate agreement or otherwise.

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September 3, 2014

Mr. Robert Jarrin
Senior Director, Government Affairs
Qualcomm Incorporated
1730 Pennsylvania Avenue, N.W., Suite 850
Washington, D.C. 20006

Dear Mr. Jarrin:

Thank you for appearing before the Subcommittee on Communications and Technology and Subcommittee on Health on July 17, 2014, to testify at the joint hearing entitled "21st Century Technology for 21st Century Cures."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Chairman
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Joseph R. Pitts
Chairman
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Communications and Technology
Frank Pallone, Ranking Member, Subcommittee on Health

Attachment

Qualcomm Incorporated

1730 Pennsylvania Avenue, NW
Suite 850
Washington, DC 20006

www.qualcomm.com

September 17, 2014

Ms. Charlotte Savercool
Legislative Clerk
One Hundred Thirteenth Congress
Committee on Energy and Commerce
2125 Rayburn
House Office Building
Washington, D.C. 20515

Dear Ms. Savercool:

On behalf of Qualcomm Incorporated, thank you for inviting me to appear on July 17, 2014 before the Subcommittee on Communications and Technology and Subcommittee on Health to testify at the joint hearing entitled "21st Century Technology for 21st Century Cures."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record has remained open to permit Members to submit additional questions for the record, and the Honorable Anna Eshoo has provided me with several questions. My responses to those questions are attached to this transmittal letter.

[redacted]

Robert Jarrin
Senior Director
Government Affairs

In response to the Honorable Anna Eshoo

1. What are your top two policy recommendations that Congress could undertake to improve the adoption of telemedicine?

Congress should improve the adoption of telemedicine by (a) considering ways to drastically expand the broad coverage, payment and pricing of telehealth and remote patient monitoring technologies by the Center for Medicare and Medicaid Services, and (b) encouraging or requiring the Secretary of Health and Human Services to waive the technical, geographic, site and service restrictions on telehealth services (as set forth in section 1834(m) of the Social Security Act) for any telemedicine and remote patient monitoring services that are delivered by Medicare Shared Savings Program (MSSP) participants.

The current Medicare telehealth provisions in the Social Security Act Section 1834(m) and the accompanying regulations are overly restrictive and exclude the majority of 21st century technology innovations. A 2012 report by a public-private task force on mHealth consisting of federal officials, academia, industry and other stakeholders, named outdated reimbursement regulations and policies as inhibitors to the proliferation of mobile health technologies.[1] These outdated provisions are limiting patient access to new technologies, effectively discouraging providers from utilizing advanced information communications technologies and solutions in their practices.[2] In fact, over the course of this Committee's 21st Century Cures hearings and roundtables, several witnesses and panelists echoed the sentiment that the biggest obstacle to health IT innovation is the issue of reimbursement and called for an urgent need to modernize outdated coverage regulations.[3]

The Centers for Medicare and Medicaid Services (CMS) covers over 100 million people and has an annual budget of nearly $900 Billion dollars. Of that amount, last year, only $10-12 million dollars were spent on reimbursement for telehealth services, according to the American Telemedicine Association. Under current Medicare coverage and payment, in order to qualify for telehealth reimbursement, the following conditions must be met: the consult must be live (real-time) voice and video (synchronous communication); it must be in a specific site of care as stipulated by CMS (skilled nursing facility, hospital, doctor's office, mental health center); the beneficiary must live in health professional shortage area (HPSA) or not in Metro Statistical Area (MSA); the service must be included in the list of Medicare telehealth services (e.g., inpatient consult, psychiatrist, psychotherapy, pharmacological, nutrition); store and forward technologies (asynchronous communications) are allowed only in Alaska and Hawaii for federal

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[1] *See* FCC Wireless Health Technology mHealth Task Force, http://www.fcc.gov/document/fact-sheet-mhealth-task-force-recommendations.

[2] *See* TIA multi-organization letter to Department of Health and Human Services (HHS) Secretary Burwell on waiving burdensome restrictions contained in Section 1834(m) of the Social Security Act for Accountable Care Organizations (ACOs) participating in the Medicare Shares Services Programs, June 9, 2014, http://www.tiaonline.org/sites/default/files/pages/Multi-Assn%20Letter%20-%201834%28m%29%20%26%20MSSP%20ACOs%20060914.pdf; ATA Telemedicine Policy Priorities, http://www.americantelemed.org/docs/default-source/policy/ata-federal-policy-priorities.pdf?sfvrsn=36; CTeL, Our Mission, September 2014, http://ctel.org/about-2/our-mission/.

[3] *See* 21st Century Cures: The President's Council of Advisors on Science and Technology (PCAST) Report on Drug Innovation, May 20, 2014, http://energycommerce.house.gov/hearing/21st-century-cures-president%E2%80%99s-council-advisors-science-and-technology-pcast-report-drug; 21st Century Cures Roundtable: Digital Health Care, June 24, 2014, http://energycommerce.house.gov/event/21st-century-cures-roundtable-digital-health-care.

demonstration projects; and the consult must be performed at distant site by a doctor, nurse, or other stipulated medical professional.[4]

In other words, 21st century solutions such as mobile medicine or remote monitoring technologies are disallowed for reimbursement, thereby discouraging their use by qualified medical professionals. This creates a disincentive to adopt modern wireless health and connected care technologies. Furthermore, under other current CMS regulations, most novel converged health and medical devices such as apps do not qualify for reimbursement as "durable medical equipment" because they are not considered "reasonable and necessary."

There are efforts underway to improve this situation. These include transitional care management codes, chronic care management codes and the creation of the Center for Medicare and Medicaid Innovation, but more needs to be done to advance the growing body of evidence that these technologies are producing, such as cost-savings, improved adherence and better outcomes.

To rectify this situation, we recommend that Congress consider ways to drastically expand the broad coverage, payment and pricing of telehealth and remote patient monitoring technologies by the Center for Medicare and Medicaid Services, and encourage or direct the Secretary of Health and Human Services to waive the technological, geographic and practice restrictions on telehealth services (as set forth in section 1834(m) of the Social Security Act) for any telemedicine and remote patient monitoring services that are delivered by Medicare Shared Savings Program (MSSP) participants. Such a waiver would provide accountable care organizations with the immediate ability to utilize advanced telehealth and remote monitoring solutions beyond current stipulated geographic limitations and through modern asynchronous technologies, thereby bringing modern healthcare to countless Medicare beneficiaries who stand to benefit from care delivery virtually anywhere and at any time.

[4] *See* CMS Telehealth Services Factsheet, April 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf.

In response to the Honorable Anna Eshoo

2. What are additional steps we can take to encourage interoperability with electronic health records, while ensuring patient privacy and HIPAA standards?

Congress should direct the Centers for Medicare and Medicaid Services and the Office of the National Coordinator for Health Information Technology (ONC) to allow patients the ability to upload patient-generated health data (PGHD) from interoperable health and medical devices into electronic health records (EHRs) as part of the meaningful use program.

Over the history of the "meaningful use" program, there have been a number of important attempts to incorporate PGHD from remote monitoring technologies into the EHR. Unfortunately, each attempt has been met with significant resistance resulting in the omission of PGHD as a requirement for EHR technology. This omission is unfortunate in light of ONCs stated goals to improve quality, safety and efficiency, while reducing health disparities.[5] Remote patient monitoring technologies such as telemedicine, telehealth and mobile health (mHealth) play an increasingly vital role in our nation's healthcare system and should be included in the Health IT Policy Committee and Health IT Standards Committee meaningful use efforts and recommendations.

Health IT is a broad ecosystem of data-driven technologies that rely on advanced remote health and medical products that are broadband enabled (wired, wireless or mobile). Health IT includes technologies that actually touch patients, electronically capturing and generating specific physiological and biometric data about a person's health state or conditions and transmitting it wherever it needs to go. Health IT serves as an umbrella term that encompasses all information driven healthcare categories and practices such as e-Care, telemedicine and mHealth.[6]

To solely focus on EHR and EHR systems ignores the interconnected value of health IT and importantly disregards significant aspects of the patient. Although health IT alone cannot heal a patient, when incorporated into the healthcare delivery system it can enable eligible care providers to make better decisions, avoid patient errors, become more efficient, and understand individual and population health more effectively.[7]

As CMS and ONC contemplate Stage 3 meaningful use, allowing the upload of PGHD into the EHR can only help ONC to achieve its goals of improving medical quality, safety, efficiency, and reducing health disparities. Stage 3 should provide concrete recommendations, references or instructions, on device interoperability to more proactively involve patients and families in their care, especially in the home or outside of healthcare institutions and facilities. Stage 3 should include instructions on PGHD and how to integrate personal data into an EHR. Stage 3 should develop a method to incentivize eligible providers to embrace the use of remote monitoring technologies, while ensuring patient privacy and HIPAA standards.

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[5] *See* ONC in Partnership with the Learning Consortium, Meaningful Use Definitions and Objectives, September 2014, http://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives.

[6] *See* FCC National Broadband Plan, Chapter 10 – Healthcarehttp://www.broadband.gov/plan/10-healthcare/.

[7] Id.

Healthcare transcends the walls of healthcare facilities whether clinical, hospital or that of the eligible professional. In today's reality, health IT facilitates continuous care and quality improvement by automating healthcare. Physiological data represents important elements of a person's health state, particularly those with high priority chronic conditions. Consistent information helps formulate a more accurate care record along the continuum of care.

As more healthcare providers and patients utilize mobile computing devices such as mobile broadband enabled smartphones, tablet PCs, and medical device data hubs, we cannot underscore how important it is that healthcare stakeholders have the ability to take advantage of PGHD throughout health IT.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

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September 3, 2014

Dr. Jonathan Niloff
Chief Medical Officer and Vice President
McKesson Connected Care and Analytics
McKesson Corporation
400th Avenue
Waltham, MA

Dear Dr. Niloff:

Thank you for appearing before the Subcommittee on Communications and Technology and Subcommittee on Health on July 17, 2014, to testify at the joint hearing entitled "21st Century Technology for 21st Century Cures."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, September 17, 2014. Your responses should be mailed to Charlotte Savercool, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Charlotte.Savercool@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Greg Walden
Chairman
Subcommittee on Communications and Technology

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Communications and Technology
Frank Pallone, Ranking Member, Subcommittee on Health

Attachment

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Jonathan M. Niloff, MD
Vice President and Chief Medical Officer
McKesson Connected Care & Analytics

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September 17, 2014

The Honorable Greg Walden
Chairman, Subcommittee on Communications and Technology
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Joseph R. Pitts
Chairman, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Re: Response to Additional Questions for the Record: "21st Century Technology for 21st Century Cures"

Dear Chairman Walden and Chairman Pitts:

Thank you for the opportunity to deliver testimony before the Energy and Commerce Subcommittee on Communications and Technology and Subcommittee on Health at the joint hearing entitled "21st Century Technology for 21st Century Cures." I am pleased to respond to the additional questions that were submitted for the record.

Responses to Questions Submitted by the Honorable Joseph Pitts

1. **You state in your testimony that "Health IT will drive quality improvements, make our care delivery system more efficient and improve the experience for patients and their families." In what ways do you see Health IT improving the lives of patients?**
   - **In your opinion, what barriers currently exist that might otherwise inhibit such potential.**

The exchange and use of health information to inform clinical decisions at the point of care will make our healthcare delivery system more efficient and will improve health outcomes for patients. Health information technology (IT) empowers all providers across the healthcare continuum to deliver more effective care and facilitates faster, more effective data exchange which results in more informed decisions that reduce errors and drive better outcomes for patients.

We cannot realize the full potential of health IT until we have a healthcare system that is driven by *interoperable* health IT. Today, our healthcare delivery system lacks a universally adopted, easy, affordable way to allow the frictionless movement of patient-centered data across all settings of care. McKesson looks forward to continuing to work with Congress, the Administration, the industry and other stakeholders towards our shared realization of a fully interoperable healthcare system.

Furthermore, promoting innovation in health IT within a 21st century healthcare system will be increasingly difficult, if not impossible, under a regulatory framework that was crafted nearly 40 years ago. We urge Congress to amend the Federal Food, Drug, and Cosmetic Act to establish guidelines that define each category of health IT, and specifically clarify that health IT will not be regulated as a medical device. Congress should then ensure that the federal government implements these guidelines according to Congress' intent.

2. **You state in your testimony that "McKesson has decades of experience serving the health IT needs of the largest and most diverse provider base in the industry...and manage millions of aggregated personal health records." What role can data aggregation and analytics play in the search for new cures?**

Aggregated data plays three very important roles in healthcare. First, aggregated data sets subjected to analytics can help and accelerate the search for new understandings of diseases and new treatments. Large aggregated data sets serve as a foundation for researchers to look for associations among multiple factors, including environmental factors and personal and genetic attributes that may provide insights into the etiology of specific diseases. Second, aggregated data sets support enhanced care delivery models that drive better, more cost-efficient care. Patients benefit from better outcomes and better satisfaction. The community benefits from a healthier population and a more cost-efficient health system. Third, data aggregation and analytics improve individual patient care and the safety of that care. Almost all patients receive care from multiple providers and facilities. The sickest patients receive care from the most providers and are most at risk. An aggregated longitudinal patient record provides clinicians with a complete view of the patient over time and geography. This improves the quality of care and improves patient safety.

3. **One of your recommendations for advancing 21st Century Cures is what you term "fully harnessing the potential of interoperable technology." In your opinion, are we talking about electronic health records alone or do you think that medical devices and other health care sources of data should also be interoperable?**

Interoperability across electronic health records should be viewed as a critically important first step. In order to fully harness the potential of interoperable technology, we believe that medical devices and other healthcare sources of data should also be interoperable.

4. **In your testimony, you mention that McKesson "supports a collaborative effort among all healthcare stakeholders to develop uniform standards, coordinated policies and the infrastructure necessary to support secure health information exchange." You then go on to mention the CommonWell Health Alliance as part of the solution to this goal. Can you explain what the CommonWell Health Alliance is? How can an effort like the CommonWell Health Alliance solve issues of interoperability that we are currently experiencing?**

CommonWell Health Alliance™ is an independent, not-for-profit trade association, founded by McKesson in partnership with our industry competitors, to create vendor-neutral services and standards that will break down the barriers currently inhibiting effective health data exchange. Today, its members include McKesson, RelayHealth, athenahealth, Cerner, Greenway, Allscripts, CPSI, Sunquest, Brightree, MacPractice, MEDHOST and CVS Caremark. The goal is to dramatically improve the quality and cost effectiveness of care nationwide by enabling seamless sharing of patient data, no matter the setting of care, with the individual's consent. Currently, services provided by CommonWell facilitate patient consent, identify and match patient records across healthcare settings, securely access clinical data in near real-time regardless of where the care was delivered, and transfer the data directly to existing health IT software systems.

CommonWell has made significant progress in the past 18 months. In the near future, patients will be empowered to manage their healthcare and better able to utilize new electronic tools to manage and authorize those who can access their medical history. Technology barriers will no longer constrain who can access a person's record; with appropriate consent, technology will instead support a trusted network for accessing and managing the delivery of the right data, to the right place, at the right time.

Responses to Questions Submitted by the Honorable Anna Eshoo

1. **What are your top two policy recommendations that Congress could undertake to improve the adoption of telemedicine?**

Currently, the Medicare Home Health Prospective Payment System and the Medicare Hospice Payment System do not allow home health or hospice organizations to bill specifically for remote patient monitoring (RPM) or telemedicine services. To improve the adoption of telemedicine, Congress could consider directing the Centers for Medicare & Medicaid Services (CMS) to authorize Medicare reimbursement for RPM and telemedicine services under these and other payment systems. In addition, Congress could encourage policies that recognize and reward the valuable role that telemedicine often plays in preventing readmissions to the hospital and the emergency department, which not only helps patients but also lowers the costs of care for both patients and the overall healthcare system.

2. **What are additional steps we can take to encourage interoperability with electronic health records, while ensuring patient privacy and HIPAA standards?**

Achieving widespread interoperability while ensuring patient privacy and HIPAA standards requires a multifaceted approach. As our healthcare system's focus continues to shift from volume to value, we should align reimbursement and payment systems to promote coordinated care powered by seamless interoperable connectivity. The Office of the National Coordinator for Health IT (ONC) should continue to provide common guardrails for exchange of healthcare information while providing flexibility within those guardrails to allow for industry innovation.

To address the current barriers to achieving widespread interoperability, McKesson recommends that the federal government prioritize the accurate identification of system users, patients and data sources. The creation of a consistent indexing service and record locating service for federated systems will accelerate the ease of exchange and improve the confidence level of both providers and patients. McKesson encourages the federal government to support the advancement of public-private initiatives to achieve these goals. An example includes CommonWell, an independent, not-for-profit trade association founded by McKesson in partnership with our industry competitors, to create vendor-neutral services and standards that will break down the barriers that inhibit effective health data exchange.

In addition, the patchwork of state laws, regulations, and local governance efforts focused on data privacy and security create substantial legal, financial and technological barriers to interoperability. Therefore, we encourage the federal government to promote and adopt uniform national policies and a governance framework that addresses patient authorization, redisclosure and secondary use to enable providers and consumers to exchange health information across state and local boundaries.

Finally, we encourage policymakers to: (1) encourage "technology neutral" open and secure application programming interface (API) technology and applications that enable bidirectional and real-time exchange of health data, (2) certify only those EHR technology products that clearly meet meaningful use program standards and support health information exchange, and (3) harmonize all data privacy and security requirements.

Conclusion
Thank you again for the invitation to provide testimony on the role that technology can play in the transformation of our healthcare system. Should you have any questions, please contact me at jonathan.niloff@mckesson.com or Joe Ganley, Vice President of Federal Government Affairs, at joe.ganley@mckesson.com.

Sincerely,

[redacted]

Jonathan Niloff, MD
Vice President and Chief Medical Officer
McKesson Connected Care & Analytics

cc: The Honorable Anna Eshoo, Ranking Member, Subcommittee on Communications and Technology, Committee on Energy and Commerce
The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health, Committee on Energy and Commerce

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